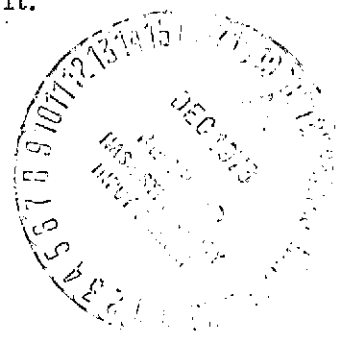


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USED AS A COUNTERMEASURE FOR
CARDIOVASCULAR DECONDITIONING (Webb
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THE DEVELOPMENT OF AN ELASTIC REVERSE GRADIENT GARMENT
TO BE USED AS A COUNTERMEASURE
FOR CARDIOVASCULAR DECONDITIONING

by James F. Annis and Paul Webb

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FOR CARDIOVASCULAR DECONDITIONING

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SUMMARY

Using a new Nomex-Lycra elastic fabric and individualized garment engineering techniques, reverse gradient garments (RGG's) were designed, constructed, and tested for effectiveness as a countermeasure against cardiovascular deconditioning. By combining torso-compensated positive pressure breathing with a distally diminishing gradient of counterpressure supplied by the elastic fabric on the limbs, the RGG acts to pool blood in the extremities of recumbent persons much as though they were standing erect in 1 g. It was theorized that through the use of a dynamic pressurization scheme, the RGG would stress the vasculature in a fashion similar to that experienced by the normally active man, hence preventing or limiting the development of post-weightlessness orthostatic intolerance and related conditions.

Four male, college-age subjects received daily treatments with the RGG during a 15-day bedrest study conducted at the NASA Ames Research Center. Four additional subjects also underwent the bedrest, but received no treatments; they served as controls. This report describes the design and construction of the garments and gives results of the treatment related measurements. The results of exercise tolerance tests and studies with lower body negative pressure, of body composition studies, and the results of a great number of blood and urine biochemistry tests are to be reported elsewhere by other investigators; however, the preliminary indication was that the RGG was somewhat effective in limiting the deconditioning process.

INTRODUCTION

Astronauts upon returning to earth exhibit varying degrees of orthostatic intolerance. Similar reactions occur when a person stands up after a period of prolonged bed rest or water immersion. Whether the hypogravic weightlessness of space is different in its physiological effects is not clear; however, it is clear that the vigorous exercise regimes of Apollo astronauts and Russian cosmonauts have not solved the problem. Physiologists have generally referred to the complex of conditions noted in connection with this phenomenon as cardiovascular deconditioning.

Although the degree of deconditioning that occurs in the individual astronaut is highly variable, it appears that its severity may be directly related to the amount of time spent in the weightless condition. The current Skylab missions may show that in-flight treatment to prevent or limit cardiovascular deconditioning should be developed for use in long duration missions. One such treatment approach is described here; it is called a reverse gradient garment (RGG).

The RGG is an elastic leotard that applies counterpressure to the body in such a fashion that blood is pooled intentionally in the extremities when a recumbent subject breathes at selected positive pressures. Using the garment attempts to simulate for the vasculature the effect of standing erect and walking in the 1 g environment.

If lack of gravity is the principal cause of the complex deconditioning process in the body, and the site of origin is the vasculature, the RGG should act as a countermeasure to prevent or limit the development of the condition. To test this hypothesis, RGG's were constructed for four test subjects, who subsequently received daily treatments with the garment while undergoing a 15-day bedrest period to simulate weightlessness. The study was conducted in the Human Research Facility at the NASA Ames Research Center, Moffett Field, California. Four additional subjects who underwent the same bedrest period but received no treatments with the RGG served as controls. This report describes the background, the principle, and the design and construction of the garments used in the study. Some results from treatment related measurements are given. The results of the physiological tests conducted by other investigators are to be reported elsewhere, but we have listed the tests performed in Appendix E.

PHYSIOLOGICAL ASPECTS OF CARDIOVASCULAR DECONDITIONING

The literature dealing with cardiovascular deconditioning is quite lengthy but often not very helpful in explaining how the condition comes about. An excellent accumulation of current knowledge is to be found in "Hypogravic and Hypodynamic Environments" (1). Vinograd and Manganelli (2) have prepared a useful summary of the literature dealing with weightlessness counter-measures.

When one simulates weightlessness by bed rest and/or water immersion, a complex of compensatory physiological reactions occurs, reactions that appear to be similar to those occurring in space flight. McCally and Wunder (3) described a more or less progressive physiological sequence thought to occur in the hypogravic condition, as follows:

1. The hydrostatic pressure in the vessels disappears;
2. there is no peripheral pooling of blood in the capacitance vessels;
3. the circulating blood volume is redistributed centrally, and the intrathoracic vasculature is filled;
4. filling results in stimulation of cardiac atrial stretch or volume receptors;
5. antidiuretic hormone (ADH) and aldosterone secretion levels are reduced via the autonomic nervous system;
6. a hyposthenuric diuresis follows;
7. this results in a reduction in total extracellular fluid and blood volume.

The loss of fluid volume may by itself account for the syncopic orthostasis, tachycardia, and narrowing of pulse pressure observed in tilt table tests and lower body negative pressure (LBNP) following weightless simulation, as well as for the orthostatic intolerance of returning astronauts. But most investigators feel there is more involved here than simple loss of fluid.

Additional clinical features associated with the deconditioning process have been reported by Lamb (4) as follows:

1. decreased muscle mass and tone
2. decreased red blood cell mass
3. reduced bone marrow activity
4. reduced coronary blood flow
5. increased storage of catecholamine products in the myocardium
6. increased nitrogen excretion
7. increased calcium mobilization and excretion

Weight loss of 2 to 5% of body weight in astronauts appears to be normal (5), even though the relationship between orthostatic intolerance and weight loss is not consistent. In addition, various workers have proposed that a loss in venous tone or reactivity results in "flabby veins," which are more compliant and passively fill (when gravity acts on the longitudinal axis), thus effectively reducing the already lowered circulating blood volume. It is presently too soon to say whether or not an adaptive mechanism developed during longer stays in space such as Skylab will lessen the physiological impact of return to gravity.

DECONDITIONING COUNTERMEASURES

Regardless of the mechanism of cardiovascular deconditioning, it is clearly a real phenomenon. A number of preventive and corrective countermeasures have been proposed and tested in the laboratory, with varying degrees of success. These techniques have included:

1. Venous occlusive cuffs on the extremities (6, 7).
2. Elastic counterpressure garments or leotards, worn on return to the upright position in 1 g (8, 9).
3. Periodic centrifugation (10).
4. Positive pressure breathing (11).
5. Lower body negative pressure.
6. Hypoxia.
7. Exercise.
8. Z-axis trampoline.
9. Pharmacologic treatment with salt and fluid retaining hormones.
10. Cardiovascular conditioning suit(CVCS)--one variety of reverse gradient garment(12).

HISTORY AND BACKGROUND

The development of an RGG required prior knowledge in closely related areas of suit technology and physiological evaluation. Webb Associates had had experience in constructing garments from powerful elastic fabrics, in the application of measured amounts of counterpressure to the body, in the use of positive pressure breathing, and in the simulation of weightlessness. Most closely related to the present project was a contract we held with the NASA Langley Research Center, in 1966, under which we had fabricated and tested a prototype cardiovascular conditioning suit; full details of this work are given in NASA CR-1206 (12).

The purpose of the CVCS was to set up a transmural pressure gradient in the circulatory system, while a subject was weightless, similar to that which exists in the erect posture at 1 g. The objective was to determine whether this pressure gradient would have a beneficial effect in preventing deconditioning of the vascular system during a prolonged period of simulated weightlessness. The suit consisted of a series of toroidal bladders enclosing contiguous sections of each limb and the torso. The bladders were filled with water and connected to individual water reservoirs whose height above the immersion tank determined the internal pressures. The helmet was pressurized to 100 mm Hg, as was the topmost bladder on the trunk. From there down to the end of the extremities, the bladder pressures decreased until the hands and feet had no pressure on them at all. The experimental condition extended through two different 2-week periods, with the subject always horizontal. The first two weeks were a control period, in which the subject lay in bed for 12 hours and was submerged in water for the other 12 hours each day, wearing no anti-deconditioning garment. During the two weeks of the CVCS experiment, he again alternated 12 hours of bed rest with 12 hours submersion, but this time he wore the CVCS during the time he was submerged, and pressurization was applied during part of this period. The result was a remarkable difference in the subject's responses following the 2-week control period and those following the period when he wore the CVCS. His response to 70° tilt after the control period was an alarming hypotension and bradycardia about the 11th minute, which caused termination of the test. After two weeks of using the CVCS, his response to tilt was normal for him and not at all alarming. The control exposure caused a reduction in his work capacity and he had a high pulse response to exercise; after the CVCS exposure, these factors were normal.

Webb Associates made a second proposal to NASA suggesting the feasibility of the elastic leotard approach to prevent cardiovascular deconditioning, but at that time the prospects for success of the basic approach were still uncertain. Since the bladder version of the CVCS produced a positive result, interest in the RGG as a possible countermeasure remained.

Meanwhile, in 1967, Webb Associates, again under contract with NASA Langley Research Center, made a preliminary study of the feasibility of using elastic fabric garments for another purpose--for protection against exposure to a vacuum. We constructed elastic sleeves and gloves for two subjects, whose arms were then exposed to near vacuum conditions while wearing these protective garments, without incident. The details of this work can be found in NASA CR-973 (13). Our ultimate objective was to build a complete suit of carefully tailored elastic fabric for wear by astronauts during EVA. Wearing such a suit, we thought, would greatly improve the astronaut's range of mobility and lessen the energy cost of their activities, which had been high while wearing conventional gas-filled pressure suits. Hence the new garment was given its name--the Space Activity Suit (SAS). In late 1967 we built the

first full suit prototype as a company project; then, from 1968 through 1970 a series of prototype SAS garments and a compatible life support system were fabricated under contract with NASA Langley Research Center. Although the SAS garments were not designed to apply counterpressure in a gradient fashion, we gained valuable experience in methods of garment engineering which was useful in construction of the RGG's. (14).

PRINCIPLE OF OPERATION

The following basic principles help to explain how the RGG functioned. In the quietly erect man of average height, the hydrostatic pressure (P_H) in the feet equals approximately 100 mm Hg. The value can be calculated by using the following relationship:

$$P_H = (\rho) g h$$

where: (ρ) = density of the blood

g = acceleration due to gravity

h = height of the column of blood

The transmural pressure (P_{VT}) at any point in the vasculature equals the sum of the blood pressure (P_B) and the hydrostatic pressure (P_H) minus tissue pressure (P_C) or intrathoracic pressure (P_I):

$$P_{VT} = P_B + P_H - (P_C) \text{ or } (P_I)$$

Tissue pressure will be considered to be constant and negligible for the purpose of this discussion.

Taking a mean P_B of 100 mm Hg, a P_H of 100 mm Hg at the feet, and a pressure drop of 90 mm Hg across the precapillary arterioles and capillaries, plus another 8 mm Hg across the venous circulation, the following values for P_{VT} are obtained for the quietly standing man:

Arterial: heart level-- $P_{VT} = 100 + 0 = 100$ mm Hg

" foot level-- $P_{VT} = 100 + 100 = 200$ mm Hg

Venous: foot level-- $P_{VT} = 10 + 100 = 110$

heart level-- $P_{VT} = 2 + 0 = 2$

When a subject is wearing the RGG, the formula for calculation of the transmural pressure takes the following form:

$$P_{VTRGG} = P_B + PPB - (\text{RGG counterpressure} + \text{tissue pressure})$$

Positive pressure breathing (PPB) is known to increase the blood pressure by an amount approximately equal to the increase in breathing pressure above ambient (15). The increased breathing pressure in the RGG helmet was counterbalanced by the external forces applied by a combination of the garment and breathing bladder. This allowed the subjects to breathe at pressures higher than normally tolerable for long periods of time without loss of fluid into tissues, discomfort, or syncope. The amount of pooling forced by the PPB-RGG combination should have been essentially equal to that experienced while standing and moving, since the applied garment pressure to the torso always varied with the breathing pressure and the limb counterpressures were fixed but decreased in gradient fashion to zero at the distal ends. For example, using the same values as above for mean blood pressure and circulatory system pressure drops, the transmural pressures which develop at heart and foot level when breathing air at 100 mm Hg are as follows:

Arterial: heart level-- $P_T = 100 + 100 - (100) = 100$ mm Hg
 foot level-- $P_T = 100 + 100 - (0) = 200$ mm Hg
 Venous: foot level-- $P_T = 10 + 100 - (0) = 110$ mm Hg
 heart level-- $P_T = 2 + 100 - (100) = 2$ mm Hg

Thus the RGG can recreate the normal erect transmural pressures. The investigator can explore a variety of levels of pressure treatment without endangering the subject. Because standing quietly erect at 1 g for longer than a few minutes at one time is not normal and may result in over-pooling with syncope ("parade ground faint"), the constant application of the 100 mm Hg gradient with the RGG for up to four hours did not seem feasible. Man is dynamic. He stands, sits, lies, walks, or is otherwise occupied for comparatively brief periods of time throughout the day. Any movement brings the so-called "muscle pump," i. e. venous pump action, into play and serves to reduce the hydrostatic effects, especially in the leg veins. Since this is true, a varying breathing pressure program was adopted for use with the RGG. The actual pressure schedule used and the rationale for its use are discussed in the "Breathing System and Pressure Schedule" section of this report; see also Appendix A. Since the elastic fabric limb portions of the garment were engineered to supply a particular gradient, i. e. as though the heart to floor hydrostatic pressure was 50 mm Hg rather than 100, and the breathing pressure both exceeded and was less than design pressures, the result was periodic overloading and unloading of the capacitance vessels. This, it was thought, would more nearly duplicate the normal vascular stresses required to maintain cardiovascular fitness. Because the subject's head was enclosed in a full bubble helmet and always pressurized externally at breathing pressure, the transmural pressures in head and brain were not affected and were similar to those obtained when lying down even though the absolute pressure was increased. Syncope did not occur, nor even threaten, during the treatments.

THE RGG SYSTEM

Each of the basic RGG systems consisted of three garment sections, a helmet and bladder assembly, and a breathing system. A necessary design criterion was that the garments had to be donned and the system made operational while the subject lay horizontal on a bed. This requirement dictated much of the design adopted. Each of the system components is described in the sections that follow.

Description of the Garments

Each of the RGG's consisted of three garment sections, which were worn in two layers. After donning a nylon brief that was commercially purchased, the subject next put on the RGG underlayer, which we often referred to as the slip layer. The lower portion of the slip layer looked much like a long-legged girdle. It was fabricated completely of elastic fabric and extended from iliac crest level to below the knee. Its construction details are shown in Figure 1; and a photograph of a subject wearing it is presented as Figure 2. The garment was designed to supply 15-18 mm Hg counterpressure

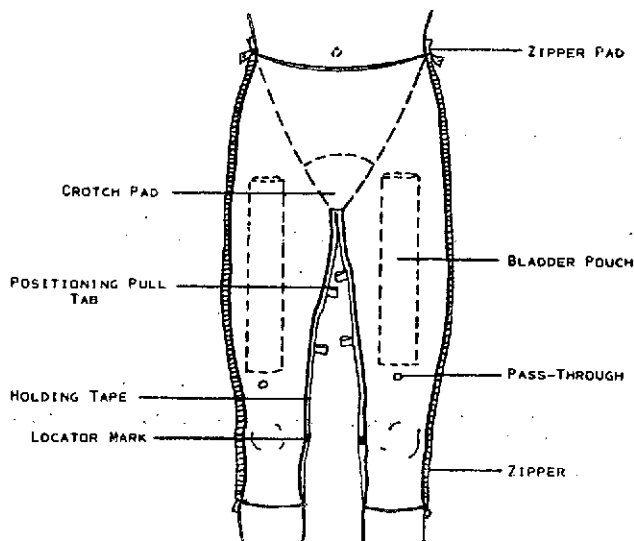


Figure 1. Line drawing of the slip layer girdle showing some construction detail.

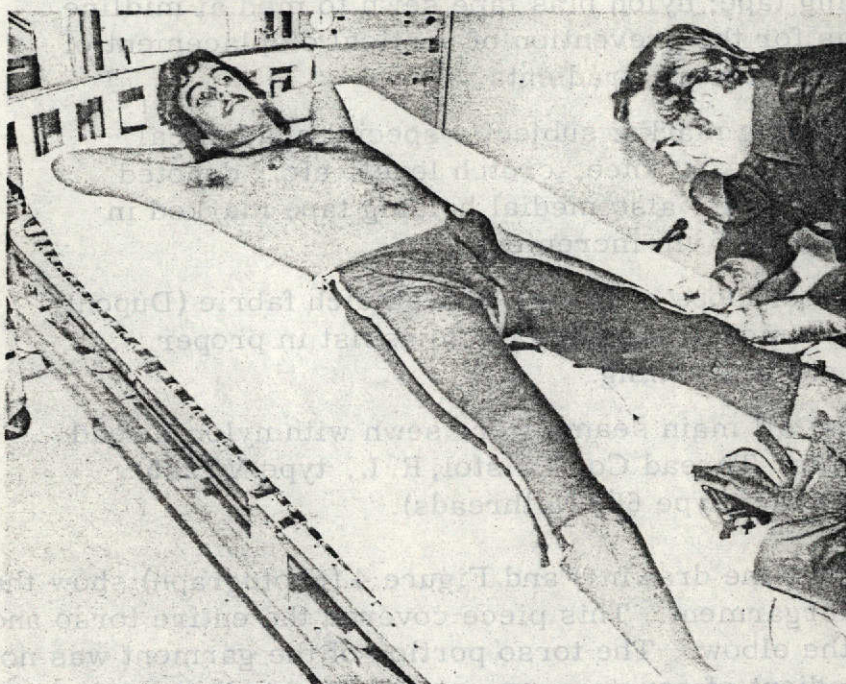


Figure 2. Photograph of subject wearing slip layer girdle.
(Picture taken during bedrest treatments.)

on the thigh at crotch level. The counterpressure was held constant above that level and reduced proportionally at 5 cm linear distances below the crotch level so that end counterpressure at the bottom was 1.5 mm Hg. The incremental decrease in counterpressure gradient was somewhat variable from subject to subject and was dependent upon the total leg length covered. Donning was accomplished via two full length lateral, jacket type zippers (open top and bottom), which were closed once the subject was rolled onto the pre-positioned garment. (All zippers were supplied by the Talon Division of Textron, Inc., Meadville, Pa.) Special features of the girdle undergarment were:

1. zipper pads: composed of 5 mm-thick foam urethane encased in a white, lightweight, nylon-spandex fabric.
2. crotch pad: bilateral and overlapping countoured, ellipse-shaped pads measuring approximately 25 cm x 10 cm wide. Same components as above.
3. bladder pouch: envelope to contain expansion bladder and/or counterpressure measuring devices (inside), with appropriately located pass-through holds for air lines and wires. Constructed of RGG fabric.

4. Holding tape: nylon bias tape sewn to medial midline seams for the prevention of vertical displacement of counterpressure gradients.
5. Positioning marks: subject's special anatomical locations, e. g. knee, crotch level, etc., denoted by red marks; also medial holding tape marked in red at each 5 cm increment.
6. pull tabs: loops of Nomex non-stretch fabric (Dupont) sewn to medial holding tape to assist in proper garment positioning.
7. seams: all main seams were sewn with nylon thread (Premier Thread Co., Bristol, R. I., type VT295) using stitch type 605 (5 threads).

Figure 3 (line drawing) and Figure 4 (photograph) show the upper portion of the undergarment. This piece covered the entire torso and the arms to just below the elbow. The torso portion of the garment was not engineered to supply a gradient of counterpressure but to supply approximately 5 mm Hg of pressure throughout. Since the garment lay under the breathing bladder, we wanted it to be form-fitting but not tight. Subsequent to fitting trials, additional fabric was added over the rib cage to lessen the work of breathing against the elastic fabric.

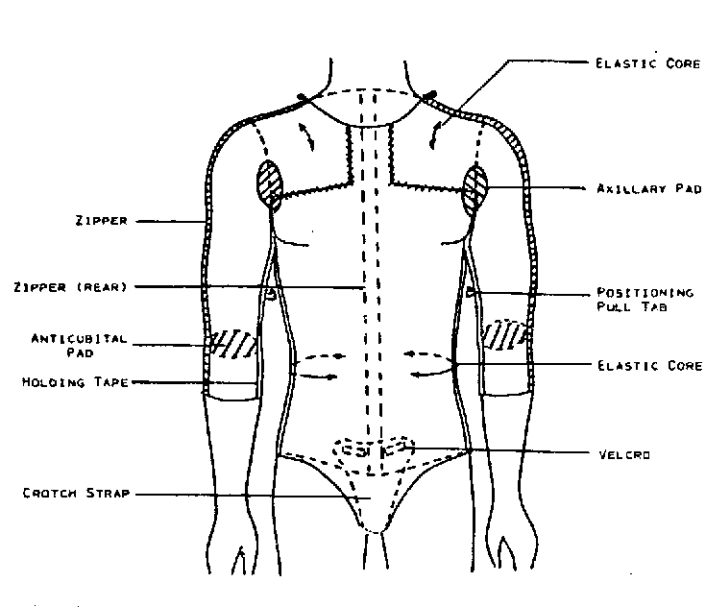


Figure 3. Line drawing of the slip layer top.

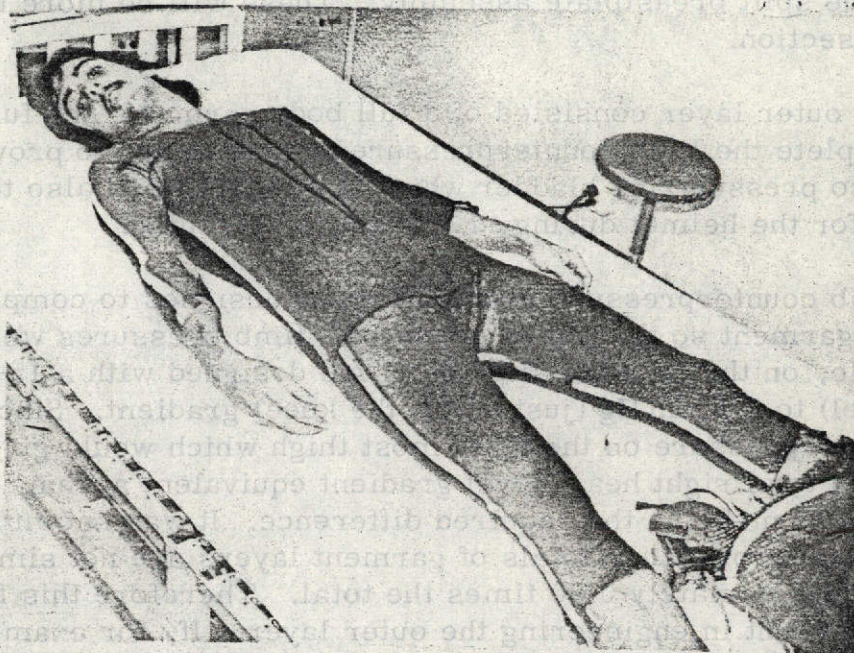


Figure 4. Photograph of subject wearing complete slip layer.
(Picture taken during the treatments.)

Sleeves were attached along the scye line and extended approximately 10 cm below the elbow. The counterpressure gradient ranged from 25 mm Hg applied at the axillary fold level linearly down to 10 mm Hg at the distal end. The actual distal end pressure, hence the gradient, varied somewhat from individual to individual; however, the overlayer pressure gradient was adjusted so that the net total pressure gradient supplied to the arms was the same for all subjects. The bottom of the torso part of the garment overlapped the interiliac area of the pelvis covered by the girdle section. This part was anchored via a strap which was passed through the crotch (front to back) and held in place by strips of Velcro (Velcro Corp., New York, N. Y.). Entry into the garment was via a full-length rear midline zipper (open top and bottom) and zippers which extended from the neck opening over the mid-shoulder line to the end of each sleeve. Donning was performed by positioning the garment on the supine subject (zippers open), closing the arm zippers, then rolling the subject 90°, closing the rear zipper, and attaching the crotch strap.

Special pieces in which the elastomic core ran vertically up and over the shoulder were inserted to improve fit and supply counterpressure to the area. Vertical length measurements from the torso were reduced 5% in the torso section of the garment to increase shoulder counterpressure and generally improve fit. In addition to axillary pads, there were pads positioned over the antecubital area to limit fabric pinching and cutting associated with arm flexion.

Immediately over the undergarment layer and next to be donned was the breathing bladder assembly, including the neck seal, lower helmet seal ring, and the split breastplate assembly. These will be more fully described in the next section.

The outer layer consisted of a full body garment, the function of which was to complete the limb counterpressure gradients and to provide restraint for the torso pressurizing bladder which lay under it and also to act as a hold-down for the helmet during the pressure breathing.

Limb counterpressure gradients were designed to complement the underlying garment so that the desired total limb pressures were obtained. For example, on the legs the slip layer was designed with a 15-18 mm Hg (crotch level) to 1.5 mm Hg (just below the knee) gradient. Since we wanted a total counterpressure on the uppermost thigh which would give an effective 50-60 mm Hg total right heart level gradient equivalent at that level, the outer garment had to make up the required difference. It was known from previous work that counterpressure totals of garment layers are not simply additive, but rather approximately 0.80 times the total. Therefore this factor was taken into account in engineering the outer layer. If, for example, a total of 40 mm Hg combined counterpressure was needed at the crotch level for a given subject, the design counterpressure had to be 1.25 times that value. Also, since the underlayer ended just below the knee and gradient calculations were based upon total heart to floor distance, the outer layer gradient was not simply linear because it assumed the full counterpressure burden below the knee. Similarly, on the arms the outer layer assumed the total counterpressure requirement below the end of the slip layer so that the combined gradient was a linear continuum of reducing counterpressure toward the wrist. The pressurization scheme of the complete assembly is given in the section of this report entitled Fabric Engineering (see Figure 15, page 32).

The same basic pattern scheme that was used in the construction of the two-piece underlayer was again used and re-engineered to fabricate the full garment. A sketch and photograph provided in Figures 5 and 6 show the detail and appearance of this garment.

As can be seen in the figures, this garment was equipped with two full-length leg-torso zippers and also arm zippers. Donning was accomplished by rolling the subject from his side onto the unzipped garment, which had been pre-positioned to be properly located when he was again on his back. The front flap created by the two torso zippers (when unzipped), which was laid between the leg sections as part of the pre-positioning process, was then placed over the subject's torso and the long zippers closed. Next the arm-shoulder zippers were closed. Finally the secondary zippers were closed over the thigh area. These zippers were added to furnish limited access ports and to make closure easier in a high counterpressure area.

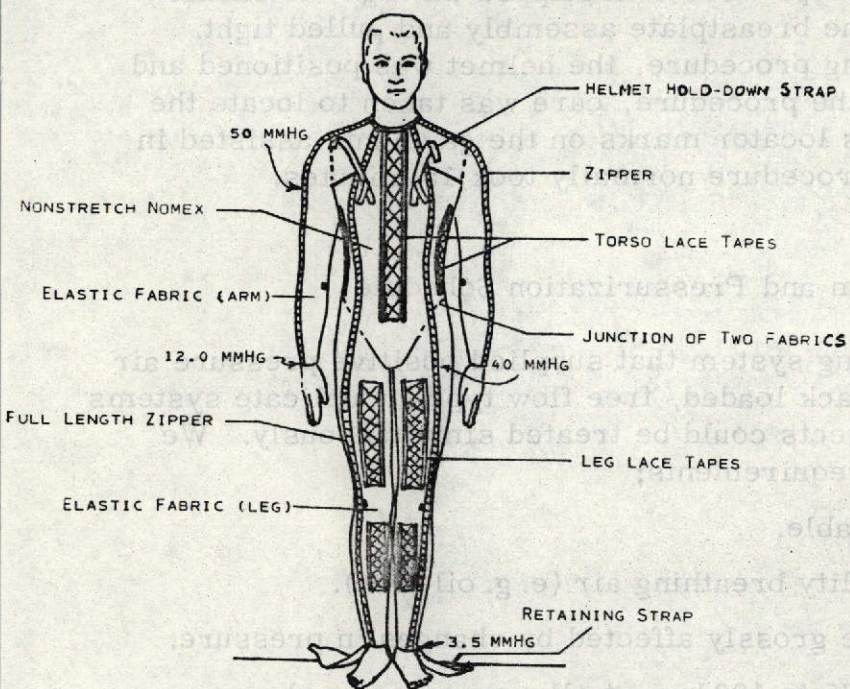


Figure 5. Line drawing of the outer full-body garment showing some design features.

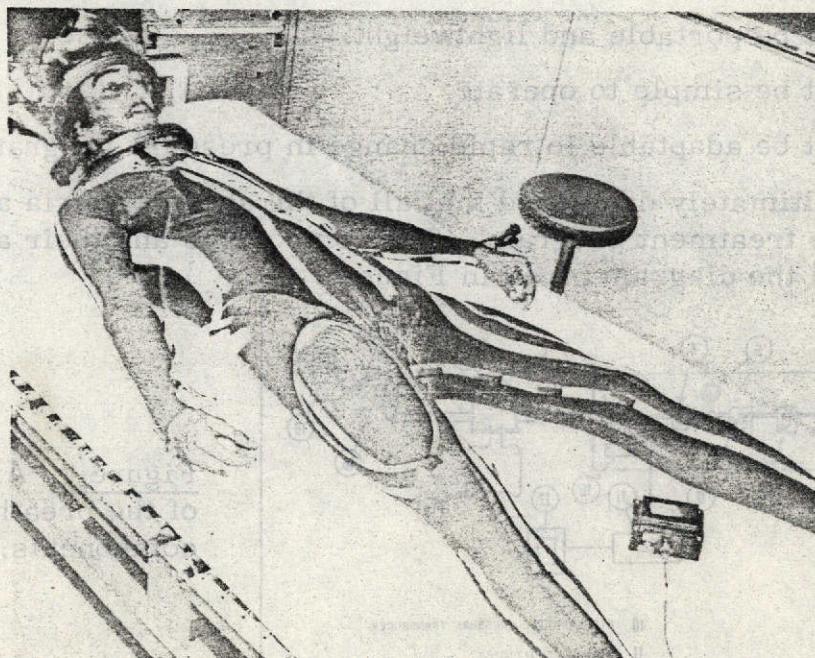


Figure 6. Photograph of subject wearing full RGG assembly, with helmet being positioned. (Picture taken during the treatments.)

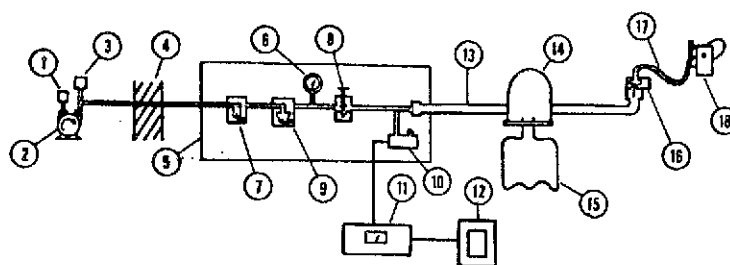
The helmet hold-down straps were then slipped through the buckle straps which were attached to the breastplate assembly and pulled tight. Finally, to complete the dressing procedure, the helmet was positioned and locked into place. Throughout the procedure, care was taken to locate the garment correctly; the subject's locator marks on the garments assisted in this job. The entire dressing procedure normally took 15 minutes.

Breathing System and Pressurization Schedule

Breathing System.--The breathing system that supplied positive pressure air to the subjects was a variably back loaded, free flow type. Duplicate systems were fabricated so that two subjects could be treated simultaneously. We developed the following design requirements:

1. Must be safe and reliable.
2. Must supply good quality breathing air (e. g. oil free).
3. Flow rate must not be grossly affected by changes in pressure.
4. Must supply at least 75 to 100 lpm at all pressures used (0 to 100 mm Hg).
5. Must be capable of programmed and automatic pressure regulation.
6. Must be portable and lightweight.
7. Must be simple to operate.
8. Must be adaptable to rapid change in pressure programs.

The systems ultimately developed met all of the above criteria and performed well during the treatment program. The components and their arrangement are depicted in the diagram given in Figure 7.



- | | |
|----------------------|-------------------------------------|
| 1 INTAKE FILTER | 10 DIFFERENTIAL PRESSURE TRANSDUCER |
| 2 COMPRESSOR | 11 SIGNAL CONDITIONER |
| 3 PRESSURE RELIEF | 12 RECORDER |
| 4 WALL | 13 BREATHING HOSE |
| 5 INSTRUMENT RACK | 14 HELMET |
| 6 PRESSURE GAUGE | 15 TORSO BLADDER |
| 7 MUFFLER | 16 PRESSURE REGULATING VALVE |
| 8 BACK LOADING VALVE | 17 FLEXIBLE MERCURY COLUMN |
| 9 FILTER | 18 PRESSURIZATION PROGRAMMER |

Figure 7. Arrangement of the breathing system components.

Air was supplied to each system by a small carbon vane compressor (Gast Mfg. Co., model no. 0440-P103A), via a pop-off valve, filter, muffler, backloading needle valve, pressure gage, and secondary safety relief to the helmet. The compressors were pallet mounted and during the treatments were located in a utility chase adjacent to the treatment room in order to isolate the noise. The remainder of the components were rack mounted and located in the treatment room. To smooth pressure fluctuations, the compressors were back-loaded to 238 mm Hg (4.5 psi). The first relief valve was set to approximately 360 mm Hg (7 psi), and the secondary relief consisted of a brass plug resting on an orifice. The weight of the plug was calculated to lift off whenever the pressure in the helmet exceeded 100 mm Hg. The air flow rate averaged nearly 100 lpm at breathing pressures of 25-50 mm Hg and was reduced to 80 lpm at breathing pressures of 100 mm Hg. Measurements of flow were made on-line during the treatments using a small turbine flow-meter (Wright spirometer, British Oxygen Co., Ltd., London, England). It was estimated that the functional volume of the helmet-bladder complex was approximately 15 liters; therefore, with a washout rate of 5 to 9 times per minute, CO₂ buildup was not a problem. Breathing pressure in each system was sensed by a differential pressure transducer (Schaevitz Engineering Co., Camden, N. J., model PTA-310D-100W). A signal conditioner serviced both transducers and the pressure of each system was monitored by a meter and continuously recorded on a strip chart recorder.

The interconnecting lines to and from the helmets were oxygen breathing hoses reinforced with wire and covered with cloth. They measured 1.9 cm (0.75 in.) ID. (R. E. Darling Co., Gaithersburg, Md., REDAR A10986-1). The length of hose (in and out) was 3 meters for the first few days of treatment. Later an additional 3 meters of hose was included in the in-coming line so that it could be coiled in an ice water bath to cool the breathing air.

Helmet effluent was routed to a back loading type of regulator, which established the system pressure. The loading of the valve was accomplished by varying the height of a mercury column. The height of the mercury loading column (hence the system pressure) was varied automatically by an aluminum cam or pressure programmer which raised or lowered the column as it turned. The cam was driven by a synchronous motor geared to produce one complete revolution of the pressure profile cam each 30 minutes. In operation the cam varied the breathing pressure over a range of pressure from 25 mm Hg to 100 mm Hg. A portion of the cam contained a movable flange which allowed a low pressure (less than 15 mm Hg) starting point. After starting, the flange was locked into the operating position. The shape of the cam was dictated by the selected pressure profile. The size and shape of the cams for the two systems were identical. A simplified sketch of the pressure regulating components of the breathing system is given in Figure 8.

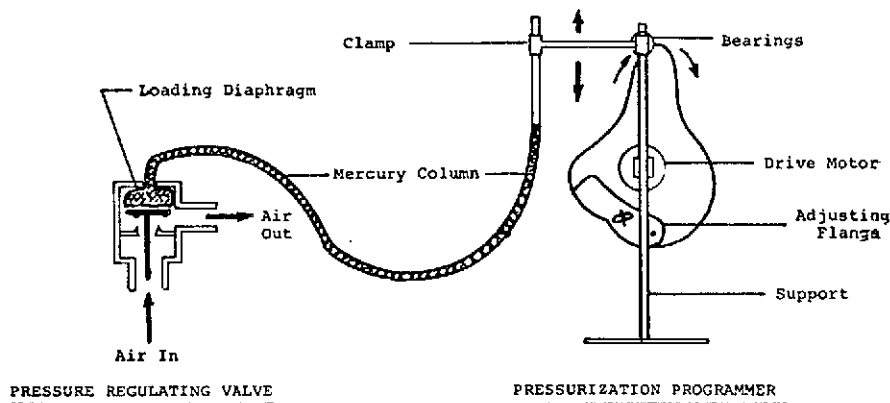


Figure 8. Sketch of the pressure regulating components of the breathing system.

The type of pressure control system used allowed considerable selectivity in treatment pressure programs. For example, if considered necessary, a single constant pressure level between 15 and 100 mm Hg could be obtained by simply turning off the cam drive motor at that point. Also the level of the selected pressure profile could be increased or decreased by changing the relative position of the back loading valve to the cam. Because of possible differences in operational pressures and flow rates in the two systems, and to minimize any possible effects therefrom, the subject-breathing system combination was switched each treatment day.

Pressurization schedule. -- There were two sets of pressures involved in the RGG: the breathing pressures and the mechanical counterpressure of the elastic suit. The suit pressures applied to the arms and legs were fixed in the suit design and tailoring. Once the suit was donned, these pressures did not change, but the torso pressure did vary with the air pressure in the helmet and bladder.

Helmet and bladder pressures, which were equal, varied dynamically during the treatment period. The reason for varying pressure was that a properly chosen schedule of pressure more closely simulated the stress of normal living on the vascular system.

The stress we were interested in simulating was the hydrostatic loading of vessels below heart level whenever a person is upright. Since normal living involves varying periods of standing, sitting, walking about, and leaning against the wall, so the hydrostatic loading varies considerably throughout a normal day. 100 mm Hg is the hydrostatic loading pressure usually given for an erect man in a 1 g environment, so a pressure schedule of four hours

at 100 mm Hg would be a simulation of a relaxed man standing upright--leaning against the wall, perhaps. When the man tenses his leg muscles or walks around, venous pressure in the foot decreases to somewhere between 10 and 30 mm Hg. When he sits, relaxed, the loading of leg and feet veins decreases to about 50 mm Hg. These considerations led to the dynamic pressure schedule depicted in Figure 9. The first portion of each 30-minute cycle was spent with a pressure in the helmet and bladder of 50 mm Hg, which was proper with the designed gradient applied by the elastic suit at the proximal ends of the arms and legs. The other portion of the 30-minute cycle was occupied with sinusoidal pressure swings between 25 and 100 mm Hg.

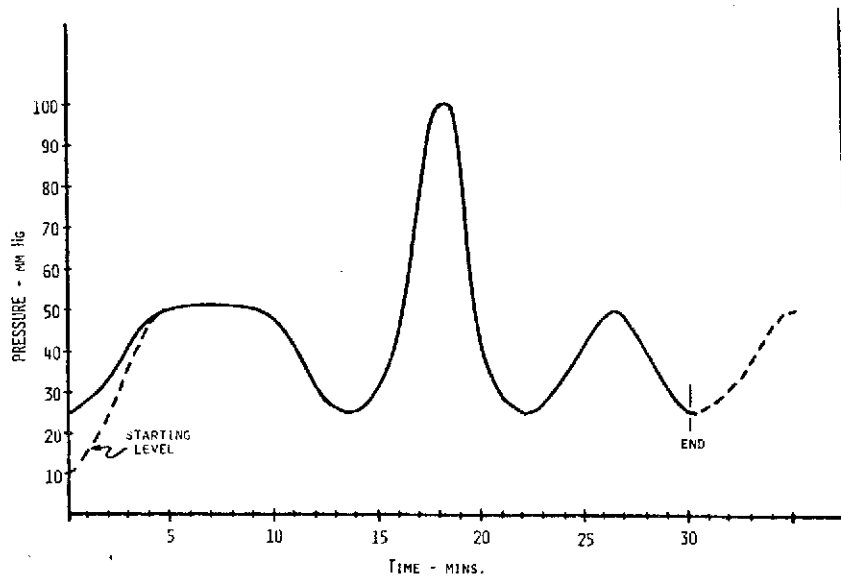


Figure 9. Curve showing the profile of the pressure schedule used during the RGG treatments.

We chose to precede the excursion to 100 mm Hg pressure with a dip to the minimum pressure of 25 mm Hg in order to permit the greatest venous return to the thorax (the greatest "unloading") which the suit would permit. This was then followed by the high pressure which caused the least venous return to the thorax--hence the greatest loading, or stress on the circulation. Finally, breathing pressure decayed through the low point again, then to 50 mm Hg, and finally to 25 mmHg to start a new cycle. A sinusoidal form was chosen as opposed to a ramp or step function change because the sinusoid was easier on the ear drums. Subjects quickly learned how to create neck seal leaks, hence lowering the pressure, especially during the 100 mm Hg peak. In so doing they occasionally experienced more rapid changes in pressures. Changes from 100 mm Hg down to 25 in as little as one second were observed. Most subjects experienced no difficulty with this maneuver. Although this form of voluntary pressure change disrupted the fixed schedule, it was not totally discouraged by the observers since it was in agreement with the goals

of the selected schedule and considered good therapy. A more complete review of the rationale for the selected pressurization schedule is provided in Appendix A.

Helmet and Bladder Assembly

Two full bubble helmets were used. The helmets consisted of a polycarbonate plastic bubble, interconnecting rings and seals, and a hinged base-plate clamp with a molded fiberglass breastplate. A torso pressurizing-breathing bladder was attached to the neck seal ring assembly. A photograph of one of the helmets is provided in Figure 10.

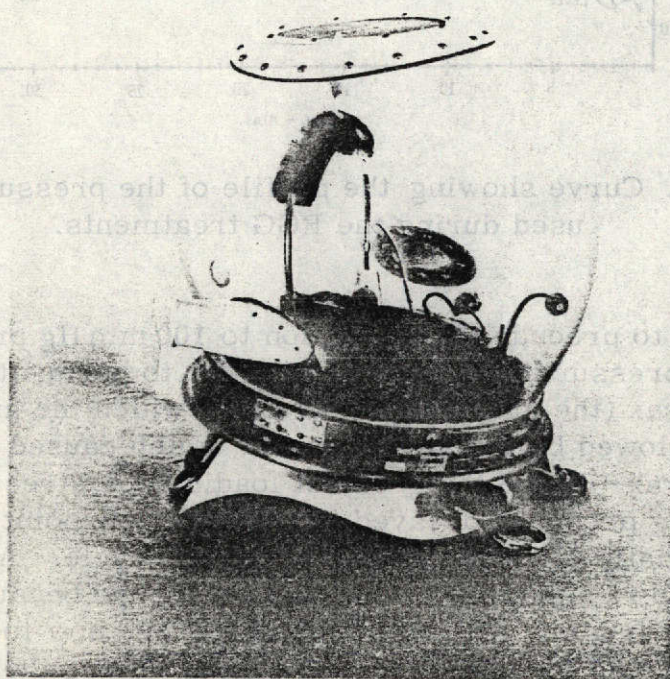


Figure 10. Photograph of one of the full bubble helmets used during the RGG treatments.

The two helmets had been used previously in our development of the Space Activity Suit (13, 14) and required some minor changes, as follows: the head-set shown in the photograph was replaced by a pillow speaker which was located on the anterior crown area of the bubble. A new microphone (Pacific Plantronics, Inc., Santa Cruz, Calif., type MS50/T55-16) and through connector were installed. The breathing air ports were replaced by aluminum fittings which opened laterally rather than dorsally. This modification was necessary to facilitate connection of the air hoses on the recumbent subjects. All seals were replaced by new material. The neck seal and reflected dam (comfort pillow) were constructed of 0.32 cm (0.125 in.) thick nyloprene. Cemented joints were hand sewn with nylon thread for safety. The helmets were leak and pressure tested to 500 mm Hg (10 psi) before use. The arrangement of the helmet and torso pressurizing-breathing bladder is shown in Figure 11.

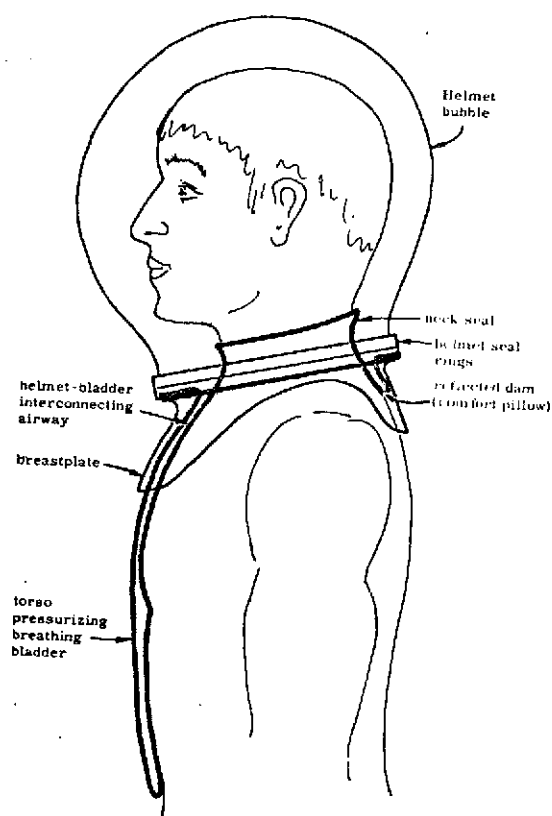


Figure 11. Cross-sectional view showing the arrangement of the helmet, comfort pillow, and torso bladder.

As can be seen, the airway was continuous with the bubble and the comfort pillow. The comfort pillow was so named because upon helmet pressurization the pillow inflated to cushion the fiberglass breastplate while pressurizing the shoulders. The entire assembly was restrained by four 2.5 cm (1 in.) wide nylon web belting straps equipped with buckles. The straps were anchored to the breastplate assembly and the outer RGG garment. Upon pressurization the force was distributed through the non-stretch Nomex fabric

of the torso section of the garment so that crotch pull even at the higher pressures used in treatments (100 mm Hg) was quite tolerable.

The torso pressurizing-breathing bladder was constructed of rubberized neoprene-nylon twill fabric (Richardson-Chemprene, Inc., Beacon, N. Y., #21433). Since the bladder was contiguous via a large opening (5 cm diameter) with the helmet air supply, the pressure in the bladder was always the same as that in the helmet. The bladder served not only to counterbalance the torso with the breathing pressure but also as a volume compensating plenum to facilitate breathing. The bladder coverage and design are shown in Figure 12, below, and also in Figure 15, page 32.

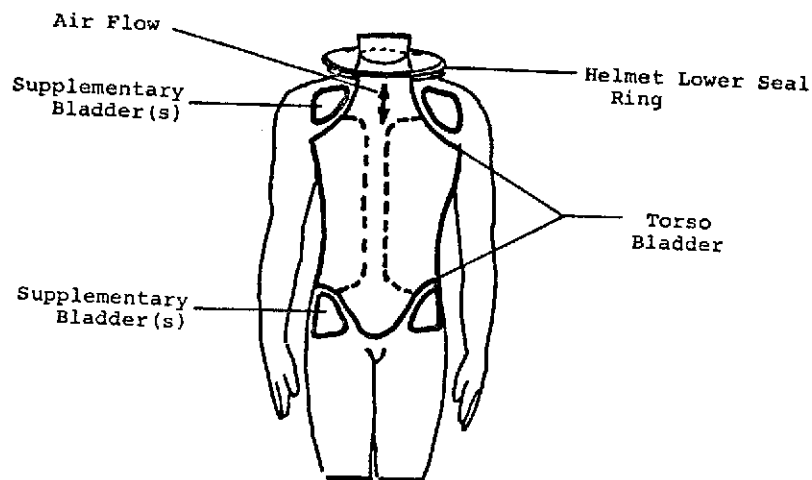


Figure 12. Sketch showing the position and coverage of the torso pressurizing-breathing bladder and the supplementary bladders.

Dimensions for sizing the bladders were taken from subject measurements. Since there were only two bladders for the four subjects, one was sized to fit the two large subjects and the other to fit the smaller two. During prototype evaluation tests, it was learned that additional coverage not designed into the original bladder was desirable. Subsequently four small supplementary bladders were added, two on the front of the shoulder and two in the groin. The bladders were not connected to the breathing air supply but were inflated either orally or with a blood pressure cuff bulb to the desired pressure. The bilateral anterior shoulder bladders acted to prevent the development of petechiae in the subclavicular area during the treatments. The groin bladders were used to increase comfort in an area where main bladder pressure ended and where the elastic pressure of the garment could not be well applied.

Expansion of the main torso bladder was controlled by adjustment of the torso lace tapes on the garment. The volume of the main bladder during operation was maintained at approximately ten liters.

GARMENT DESIGN AND CONSTRUCTION METHODS

One of the early tasks in the RGG project was writing specifications and placing a subcontract for the development of a new fabric, which ultimately proved to be very satisfactory. In order to tailor the garments and engineer specific counterpressures, we had to know not only the physical properties of the fabric but also the dimensions of the person to be fitted; therefore the test subjects were selected as early in the project as possible. The four subjects selected to wear the RGG were measured in great detail. Meanwhile, during fabric production and subject selection and measurement, design studies had resulted in a preliminary pattern layout for garment construction. The subject measurements were then prepared for sizing the individual pattern pieces of each garment. Using a laboratory technician as subject (who had also been measured), a series of prototype garments was fabricated. The information gained from design, fit, donning, and counterpressure measurements on these garments was used in the fabrication of the final test garments. Meanwhile, related instruments and hardware to complete the RGG system were being purchased or fabricated. A series of complete system test runs was made in our laboratory, using the technician as subject, wearing his prototype test garments. As a result of these tests, a number of corrections and modifications were incorporated into the final test assemblies. The total production time from subject selection to the start of the bedrest study at Ames Research Center was 4-1/2 months.

The above paragraph outlines the RGG production tasks as they were performed in the project. In the following sections, each of the various aspects of the design and production of the RGG's will be dealt with.

Fabrics

Early in the project specifications were issued for a new fabric to be developed for constructing the RGG's. We felt that a new fabric was required for the following reasons:

1. Past experience with available elastic fabrics had shown that they all had one or more undesirable characteristics, such as poor retention of original physical properties, poor sewability, poor hand (feeling to touch), tendency to ravel, limited porosity, limited elongation, or low power.

2. A comprehensive physical description and test of the fabric, usually not available with "off-the-shelf" fabrics, were needed.
3. We could make a start toward a space-qualified fabric by incorporating properties such as low flammability.

The specifications were sent to three possible suppliers, and the subcontract was ultimately awarded to a firm specializing in fabric development, Prodesco, Inc., of Perkasio, Pennsylvania.

Many types of elastic fabrics are available today, both woven and knitted, made of fibers including many kinds of rubber filaments and various synthetics. One synthetic that has found wide commercial use is spandex, a species within the polyurethane elastomer group. In elastic fabrics, the elastic fibers usually run parallel through the length of the fabric matrix (warp or wale) and are held in position by cross fibers (weft, courses) of a non-elastic yarn (see Appendix B). Spandex elastomers have particularly good specifications with regard to elongation, set, shelf life, and inertness. The four major types of elastic fabric are bobbinet, powernet, tricot, and circular knit. We have had most experience in working with bobbinet and powernet, since these were used to construct the Space Activity Suit garments.

Using powernet fabrication procedures, our subcontractor, Prodesco, produced 14 variants, from which one fabric constructed of spun Nomex and Lycra (both DuPont) spandex yarns was selected as possessing properties nearest to those specified. A limited production run was made, but the finished fabric was not usable because of a high number of defects. Since the problem appeared to be related to the Nomex yarn used, a second run was made using a different Nomex yarn that had been used successfully before. The resulting fabric (sage green in color) had physical properties very similar to the first but its defects were minimal. It was this fabric from which the elastic segments of the RGG were constructed. A complete description of the fabric including the test data, as prepared by the fabricator, is presented in Appendix B.

As described earlier, the torso section of the full body garment was constructed of a non-stretch fabric, which served two purposes. It acted to retain and shape the inflated bladder, and it served as the helmet restraint base to prevent or limit the helmet rise associated with pressurization. At the highest breathing pressure, the fabric had to restrain a vertical force of approximately 70 lbs. The pull was transferred largely to the elastic thigh portion of the garment, and crotch pull even at 100 mm Hg helmet pressure was quite tolerable. The non-stretch fabric was 100% Nomex, sage green, and was originally developed for construction of U.S. Air Force anti-G suits. A listing of the physical properties of this fabric is given in Appendix C.

Subjects and Measurements

Selection.--From the group of subject candidates interviewed, eight were selected to participate in the study, four to be suited with the RGG and four as controls. All subjects were male college students. Placement in the treated or control groups was based upon individual willingness to wear the garment, group pairing based upon height-weight relationships, and the result of preliminary orthostatic tolerance and fitness tests performed in the Webb Associates laboratory. The objective was to balance as closely as possible the physical and physiological characteristics of the two groups. Prior to final selection, subjects were fully instructed about all aspects of the testing protocol and voluntarily signed the human research informed consent forms. Also, complete medical exams had to be passed. As a result of the medical exams, one of the original eight subjects was dropped and later replaced by control subject GL (#5). Two groups, each composed of two treated and two control subjects, were formed, and each subject was assigned a test number. Basic anthropometric data for all eight are presented in Table 1, below.

Table 1.
Basic Physical Characteristics of the Subjects

		Subject # & initials	Age*	Stature		Weight	
			yrs	cm	percentile**	kg	percentile**
Group I	suited	1 FF	21	177.1	49	85.5	76
	"	4 DS	22	184.3	87	69.5	17
	control	2 TC	21	176.5	45	84.1	72
	"	3 RR	20	179.1	62	70.5	21
Group II	suited	7 TH	20	170.5	14	60.7	2
	"	8 AH	19	181.6	76	73.2	30
	control	5 GL	26	174.0	30	75.5	38
	"	6 MS	20	179.1	62	72.7	28

* At time of selection.

** Percentiles based upon values from Anthropometry of U. S. Air Force Flyers--1967 Survey. (Unpublished data, Anthropology Branch, Aerospace Medical Research Laboratory, Wright-Patterson Air Force Base, Ohio.)

Measurements.--Since the RGG had to be carefully fitted as well as engineered for proper counterpressure gradient application, the subjects for whom suits were constructed had to be thoroughly measured anthropometrically. A total of 320 discrete measurements was taken on each of the four subjects who were to be fitted with RGG's. Approximately 100 of the measurements

can be considered classical anthropometric descriptors, and the remainder were needed for tailoring and engineering purposes. All measurements were performed manually by experienced anthropometrists using standard anthropometers. All measurements were recorded to the nearest millimeter on prepared forms. So that the suited subjects can be physically characterized, a group of selected measurements is given in Table 2. Procedures used for the more standard measurements, as well as selection of landmarks, were based upon techniques used in recent anthropometric surveys (16). All measurements were taken with the subject standing, after some discussion about the measurement of leg circumferences. Should they be taken with the subject lying down, since the garments were to be worn in bed? We decided not to do this, since the dimensional increase that occurs relative to hydrostatic blood pooling in the erect person's limbs should be included in suit pressure gradient calculations.

A preponderance of circumferential or girth measurements was needed for garment pressure engineering. The reason for this is explained in the next section of this report (Fabric Engineering). Since the procedures used for obtaining these and other special tailoring measurements are not standard, a brief outline of the methods used is given below:

1. Lateral midlines for the legs and torso from the floor to the axilla were defined and marked on the skin, using a colored, fine felt-tip pen.
2. Starting at the tip of the lateral malleolus (zero level), ink marks were made on the lateral midlines at 5 cm increments. A flexible steel measuring tape, made to conform to body contours and divided into millimeters, was used.
3. Special anatomic landmarks, e. g. calf maximum girth level, patella, crotch, iliac crest, nipple level anterior, axillary fold level, etc., were located and marked on the lateral midline wherever they fell.
4. With the arms in the anatomic position (thumbs out), the lateral midline-5 cm increment grid was drawn on the skin of the arms.
5. Special features of the arm, e. g. forearm maximum girth level, elbow, mid biceps, etc., were denoted on the line.
6. On the torso from crotch to suprasternale (front), and coccyx to cervicale (rear), the medial midlines were drawn. The zero level mark for the lines was referenced to the nearest 5 cm mark on the lateral midline.

7. All anatomic landmark levels of the torso were also marked on the medial midline.
8. Each shoulder arch was divided into anterior and posterior halves along the mid-shoulder line and then ruled horizontally and vertically in a 5 cm grid pattern. This area covered from the level of the axilla laterally to the extension of the neck angle line both front and back.
9. With all measurement points located, the leg and torso circumferences were obtained every 5 cm, progressing from the zero reference upward.
10. Above crotch level, all circumferences on the torso were recorded as portions of the quadrant defined by the midline marks.
11. The arm-shoulder complex was measured similarly.

Throughout the measurement procedure an effort was made to eliminate errors in transcription of values or errors induced by tape pressure, skin deformation, or subject movement. A number of new and special measurements were developed; this was particularly true for the crotch and shoulder areas, which were known to be difficult to fit.

Fabric Engineering

When subject dimensions and fabric properties are known, it is possible to produce a selected counterpressure to be provided by the finished garment over a specific body site, although this is strictly true only for the more cylindrical portions of the body. The pattern size is dependent upon the counterpressure to be applied on a given diameter and the amount of stretch the fabric must undergo in order to supply that counterpressure. The amount of force or tension on the fabric when stretched is a function of the elastic modulus of the fabric and must be known. This value is simply the ratio of the applied extending force or stress, as expressed per unit length of fabric, to the proportionate change in length from the unloaded value (extensibility ratio). Stress-strain or power curves for an elastic fabric are determined on a textile testing machine, and are usually expressed in terms of percent elongation (as compared to the original length of the test piece) at a given force per unit width of material. Power curves at three different loading levels were determined for the powernet fabric used in RGG construction. Curves for the finished fabric in the wale direction have been reproduced in Figure 13.

Table 2.
Selected Measurements of the Treated Subjects¹

<u>Measurement</u>	<u>Subject</u>			
	FF	JH	AH	DS
<u>Weight²</u>	85.5 kg	60.7 kg	73.2 kg	69.5 kg
<u>Heights:</u>				
stature	177.1 cm	170.5 cm	181.6 cm	184.3 cm
3rd intercostal space--right ³	133.2	129.3	136.6	142.0
cervicale	150.2	143.5	153.3	156.3
chin	153.5	145.7	156.4	160.7
suprasternale	143.4	137.6	147.1	148.1
acromiale ⁴	144.1	138.9	144.9	149.2
crotch	85.3	78.7	83.2	88.6
dactylion ⁴	65.1	69.2	66.3	68.4
trochanteric ⁴	---	88.3	98.7	97.3
patella circumference ⁴	49.1	45.6	49.6	51.4
medial malleolus ⁴	8.8	8.3	8.9	9.2
<u>Lengths-Breadths</u>				
Head length	18.0	19.8	18.5	19.9
head breadth	14.2	14.9	13.2	15.0
biacromial breadth	43.8	38.4	42.2	39.4
acromion-radiale length ⁴	29.3	19.0	30.5	35.3
radiale-styllion length ⁴	23.5	31.5	26.5	26.9
hand length ⁴	21.0	17.5	19.6	19.4
hand breadth ⁴	8.7	8.1	8.8	8.5
foot length ⁴	26.4	25.5	27.4	27.4
foot breadth ⁴	11.2	9.5	10.2	10.5
elbow bony breadth (humerus) ⁴	7.4	6.3	6.9	7.1
knee bony breadth (femur) ⁴	9.0	---	8.9	---
<u>Circumferences</u>				
vertical trunk circumference	167.5	160.0	166.2	162.6
hip (maximum buttocks)	98.7	86.9	98.5	95.5
chest (nipple)	105.7	85.2	92.8	83.8
ankle ⁴	23.4	21.7	21.8	23.4
calf (maximum) ⁴	38.6	34.6	35.9	39.0
waist (omphialon)	86.5	75.8	78.2	73.0
scye ⁴	50.6	38.6	44.5	37.1
biceps (relaxed) ⁴	31.7	27.7	25.5	27.0
forearm ⁴	29.6	24.8	24.9	25.6
wrist ⁴	17.7	16.2	15.3	16.6
neck	40.3	36.3	37.5	33.6

Table 2.
Selected Measurements of the Treated Subjects

<u>Measurement</u>	<u>Subject</u>			
	<u>FF</u>	<u>JH</u>	<u>AH</u>	<u>DS</u>
<u>Skinfolds</u> ⁵				
subscapular (R)	11.5 mm	8.0 mm	14.0 mm	6.5 mm
triceps (R)	6.5	4.5	5.0	8.0
juxtanipple (R)	6.5	2.5	5.0	3.0
suprailiac (R)	20.0	8.5	13.0	8.0
mal-xiphoid (R)	10.5	4.5	13.0	5.0
calf (R)	8.5	5.0	7.0	8.5

¹For methods, refer to: Anthropometric Survey of Turkey, Greece, and Italy, by H. T. E. Hertzberg, E. Churchill, C. S. Dupertuis, R. M. White, and A. Damon. The MacMillan Co., New York, 1963 (16).

²At time of measurements.

³Used as hydrostatic pressure zero point (2 cm right of sternum).

⁴Value quoted is average of right-left measurement.

⁵Harpender caliper.

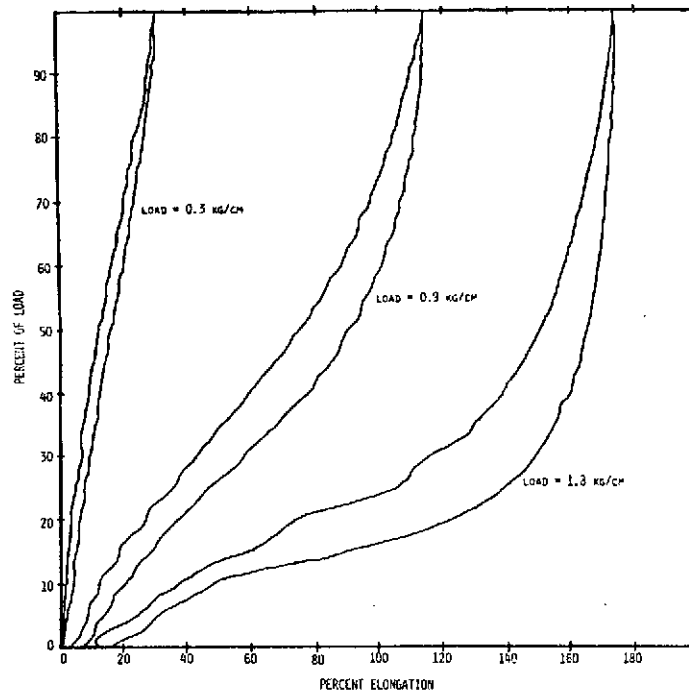


Figure 13. Stress-strain or power curves at three load levels for the elastic fabric used in RGG construction. Curves are reproduced from the originals supplied by the fabric manufacturer.

The relationship between the tension (elongation force) and the counterpressure follows the LaPlacian principle, which in its simplest form is:

$$P = T/r$$

where P = the applied pressure, T = the tensional force, and r = the radius of the part to be fitted. (For a more complete review of the derivation of the above expression, see our earlier report on the development of the Space Activity Suit (14).) The appearance of a radius term in the hoop tension formula explains why so many circumferential measurements were taken on the subjects. Since a great number of calculations was required to construct the pressure gradients on the limb sections of each garment, we wished to be able to go directly from each discrete subject measurement to "cut-length" of the relaxed fabric on the garment patterns. This was accomplished by computerization of the power curve data for the fabric in combination with a modified version of the hoop tension formula for a range of circumferences. Using a piece-wise linearization technique, equations were derived for the 0.3 and the 0.9 kg/cm power curves of the fabric (see Appendix B and Figure 13, above.) The resultant program used is given in

Appendix D. The format used permitted reading fabric "cut-lengths" directly from the print-out for circumferences ranging from 10 cm to 100 cm in steps of 0.25 cm for pressures of from 1 to 49 mm Hg in steps of 1 mmHg each. After each individual's pressure gradient level was determined at each circumferential measurement point, one-half working scale patterns were drawn on graph paper. Next, a full scale pattern was constructed for each garment piece. Figure 14 shows a scaled example of the working layout for a leg pattern piece. As shown in the figure, all engineering data relative to a particular pattern piece were maintained on the 1/2 scale graphic layouts for a working base and reference. All measurement details, including special anatomic features, were carefully marked directly on the elastic fabric as it was cut.

Additional special considerations that were used in the construction process included the following:

1. The hoop tension formula used in the computer program was modified to include a factor for change in thickness of the fabric with elongation. This factor was derived empirically.
2. The general guideline was used which precluded the use of the fabric to supply more counterpressure than was obtainable at 80% elongation (of "cut-length") over a given circumference.
3. Adjustments were made in cut-lengths to account for seaming and insertion of non-stretch components such as zippers.
4. Agreement with $\pm 10\%$ between calculated and measured counterpressures at a given point was considered necessary to prove the validity of the method.
5. To prevent vertical distortion and/or dislocation of the garment when donned, holding tapes and non-stretchable zippers were located strategically.

Since the garments were designed and constructed with a fixed pressure gradient on the limbs, we were anxious that some degree of adjustability be included. If significant weight loss were to occur during bed rest (which it did not), the garments would need to be re-tensioned in order to maintain the original gradient pressure level. Also, if a treatment program or pressure level needed to be altered, the garments should be equipped to handle the change. Both of these objectives were accomplished by the insertion of lace tapes and bladders in the leg sections of the garment. No provision for altering arm counterpressure was made.

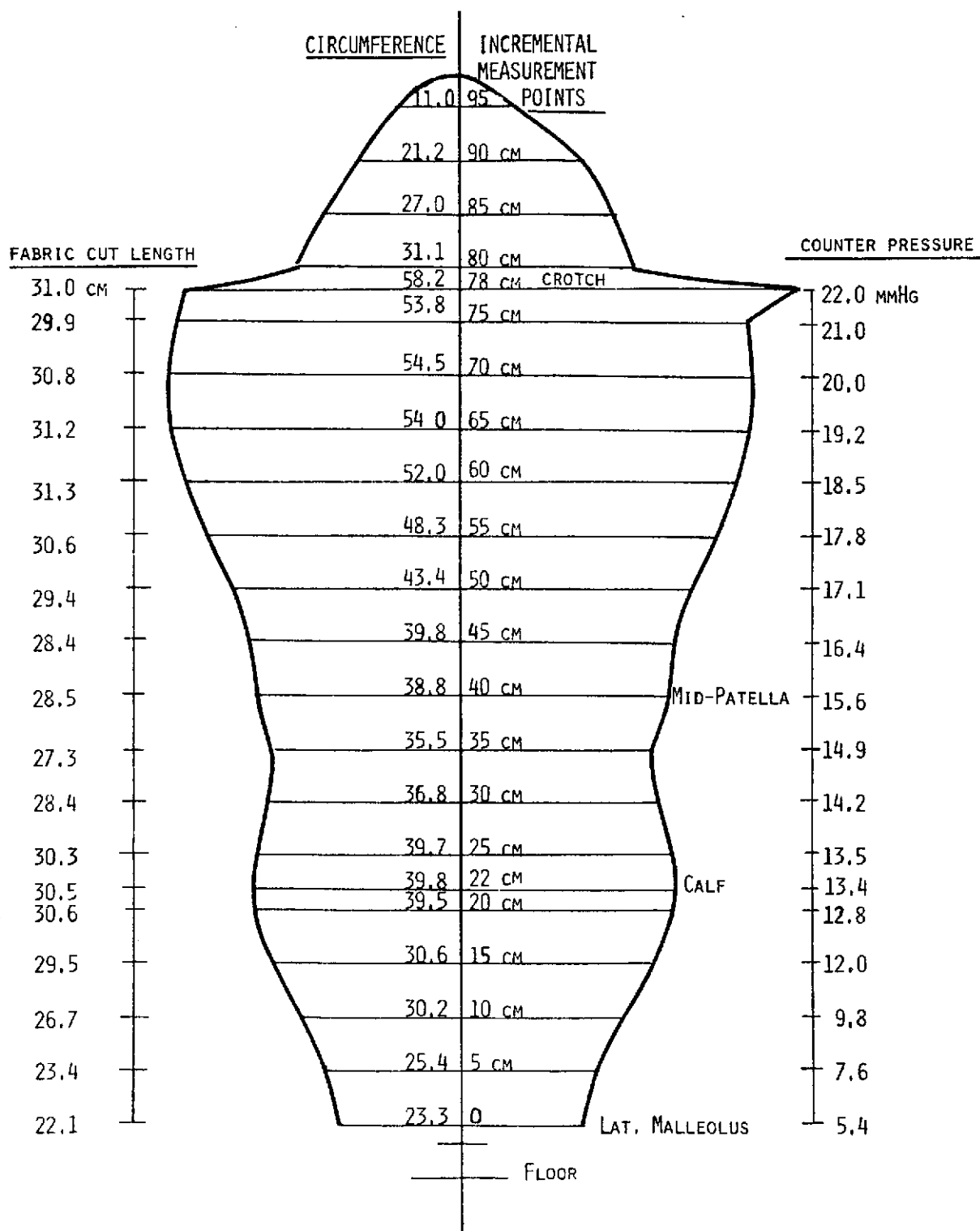


Figure 14. Reproduction of a working layout leg pattern for an actual RGG full body garment.

The lace tapes, similar to those used in partial pressure suits, were made of white nylon (Sherman Textile Corp., Pawtucket, R. I., #S/903). They were located over the thigh and calf region of each leg but interrupted across the knee joint. The loop tapes were spaced so that a given increment of tightening resulted in a known amount of increased counterpressure while retaining the gradient scheme. For example, 2 cm of take-up in the laces over the length of the tape would increase the pressure by 10 mm Hg. Lace tapes were also sewn to the anterior midline and lateral midlines of the non-stretch Nomex over the torso area. These served to control the size of the inflated breathing bladder (see Helmet and Bladder Assembly).

Provisions were made for the insertion of pressurization bladders underneath the lace tapes; they were constructed of the same neoprene-nylon fabric used to make the large torso bladder. These bladders were removable and inflated independently of the breathing system. They were designed to supply an additional 5 mm Hg of counterpressure along the gradient when fully inflated. Also, it was intended to use these bladders under tightened lace tapes to prevent pinching.

The counterpressure supplied to the body by the complete RGG assembly is shown in Figure 15. The pressurization of the torso varied between 20 and 100 mm Hg and followed the pattern established by the breathing pressure schedule (see Breathing System and Pressurization Schedule). The pressure gradients on the limbs were fixed by the elastic fabric engineering and were basically the same for all subjects. As described above, the leg counterpressure gradient could be increased through the use of bladders and lace tapes, if required. The only areas of the body where the counterpressure cannot be accurately stated correspond to the location of the supplementary bladders. Since exact engineering of the fabric could not be performed for these areas, proof of proper pressurization relied upon prevention of localized low pressure effects during operation, e. g. petechiae and edema. The decision not to include the torso below the heart level in the gradient of pressure was based upon the suspicion that a gradient of pressure would not properly transfer to the abdominal vasculature and that a large amount of blood pooling might occur there. The RGG was designed to preferentially stress the limb vasculature, which we considered to play a large role in the deconditioning process.

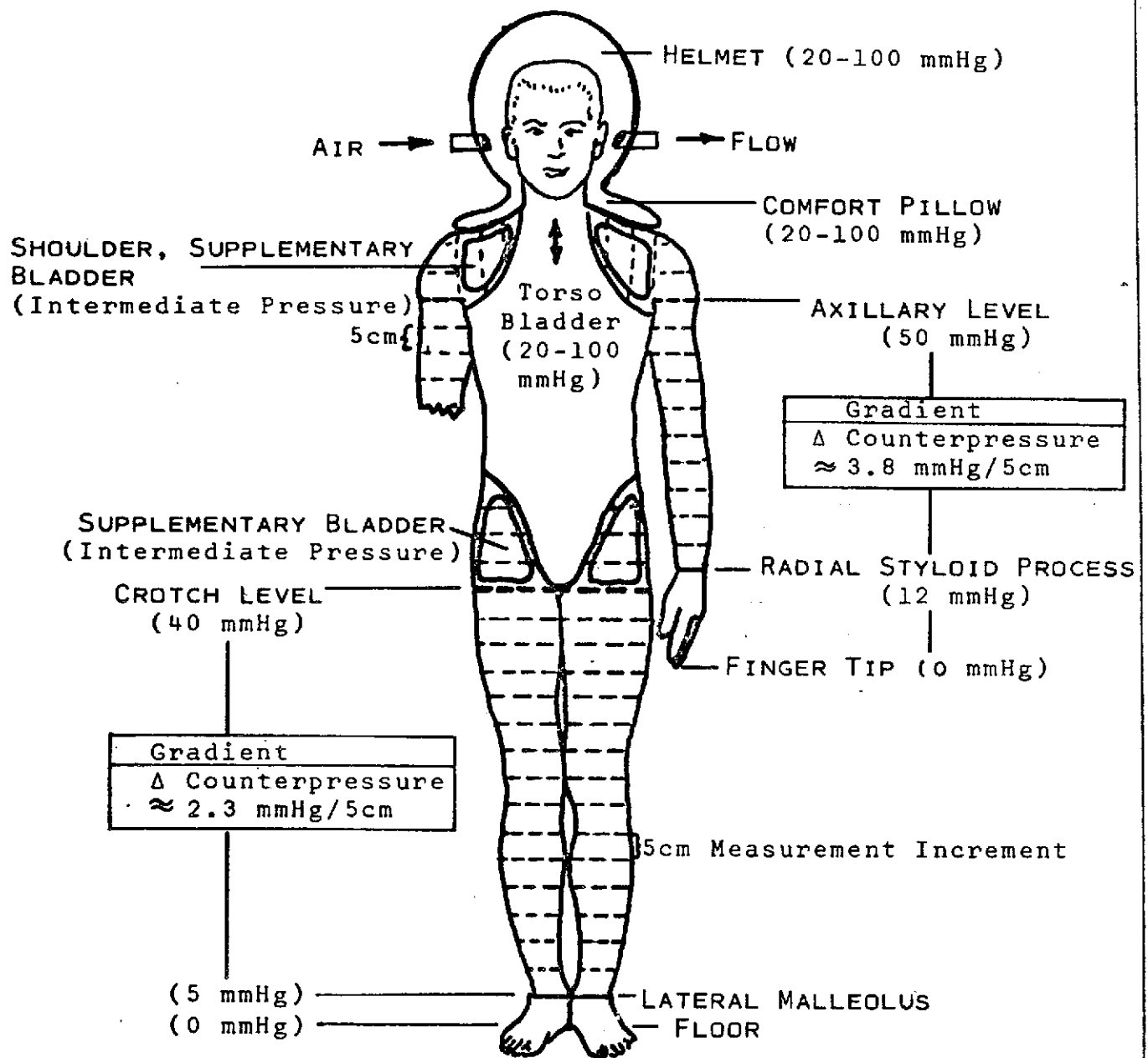


Figure 15. Sketch showing the pressurization scheme of the complete RGG system.

ACCESSORY EQUIPMENT AND METHODS

Counterpressure Measurement Device

The tightness of fit progressing centrally on the limbs, the visible change in spacing of the fabric threads and elastic core along the limbs, and the obvious peripheral venous engorgement in the hands and feet, were all evidence that the RGG's were producing a gradient of pressure. However, these observations said little if anything about the actual level of counterpressure applied at a particular point under the garment. A method for determining the suit applied pressure at the skin-cloth interface was therefore developed. From our previous experience we had learned that available miniature pressure transducers were not satisfactory for this purpose. For accuracy of measurement at the relatively low pressures to be sensed under the RGG, the transducer had to be quite large in area but also had to be thin. We had tried pressure sensitive wafers, piezoelectric disks, but with limited success, since repeatability is poor. For bench testing of counterpressure we have found the blood pressure cuff bladder and gage to be a satisfactory method. However, the standard bladder is large and thicker than preferred. Also the counterpressure is taken to be that pressure which occurs at the instant the bladder first starts to expand. The detection of this instant requires the use of a motion detector of some sort. For this purpose we have used instruments which measure change in limb girth (see venous compliance test--Helex). This method was considered unsatisfactory for use during the bedrest testing. In this study we used another variation of the inflated bladder technique. The sensor used is similar to a pressure switch in concept. The device is depicted diagrammatically in Figure 16. Once in place under the garment, air was pumped into the bladder. At that point when bladder pressure equaled applied pressure the bladder expanded, the contacts separated, and a battery powered light went off. Bladder pressure was simultaneously monitored on an aneroid gage.

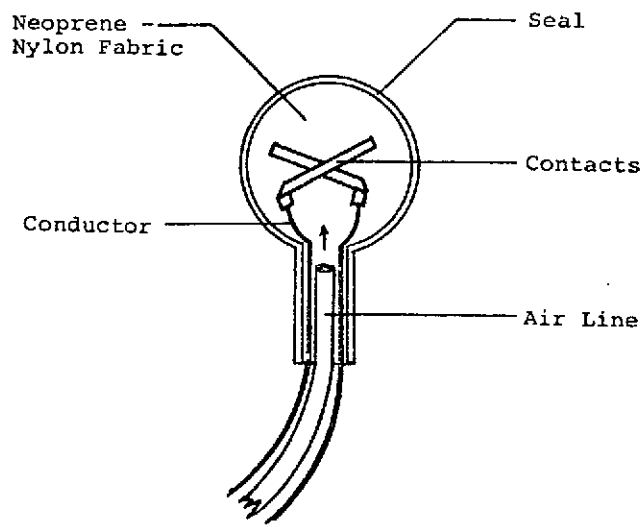


Figure 16. Line drawing showing internal detail of the garment counterpressure sensor. Top bladder cover removed to show detail.

Bladders were constructed of rubberized nylon fabric and sealed around the edges. The contacts were of 200 mesh stainless steel screen wire, 1.5 mm wide. The inflation tube was 3.175 mm OD x 1.6 mm ID plastic tubing. Two sizes of bladders were fabricated, with an effective inflation area of 12.5 cm² and 6 cm². The bladders were approximately 1.5 mm thick, and so did not appreciably distort the skin or the fabric. The bladders were usually positioned in the garment just prior to closing. All transducers were bench calibrated using a recorder to detect true pressure endpoints. To simplify operation during the test, the squeeze bulb, signal light, aneroid gage, connecting lines, and battery pack were incorporated into a single instrument cabinet.

Venous Compliance Measurement

Because quantitative data indicating the extent of cardiovascular deconditioning occurring during the two weeks of bed rest were desirable, we performed a simple test of venous compliance on both RGG and control subjects. The technique used was similar to that reported by Newberry and Bryan (17) and utilized by Blockley and Friedlander in the evaluation of the Langley Cardiovascular Conditioning Suit (12). The basic measurement from which venous compliance is computed is the change in arm girth as a function of occlusion pressure of the arm veins. The procedure consisted of applying a series of cuff pressures to a carefully supported arm with a standard blood pressure cuff while changes in forearm girth were sensed by a variable-inductance linear transducer connected as one arm of an impedance bridge (Helex Girth Measurement System, Physiometrics, Inc., Malibu, California). Output of the bridge is directly and linearly proportional to the expanded length of the gage.

The stepwise measurement procedure used is as follows:

1. Place arm in arm suspension system (relaxed, at approximately 45° above body horizontal plane).
2. Position blood pressure cuff loosely in the standard clinical location.
3. Position pre-calibrated girth change transducer at approximately 5 cm distal to antecubital fold.
Gently massage forearm around transducer.
4. Inflate cuff slowly to 60 mm Hg (1 min.); maintain for 3 mins; read expansion meter; record.
5. Reduce cuff pressure to 40 mm Hg--read at 1 min.
6. Reduce cuff pressure to 20 mm Hg--read at 1 min.
7. Reduce cuff pressure to 0 mm Hg--read at 1 min.
8. Remove cuff and transducer; free arm from suspension assembly.

The total elapsed test time was seven minutes, not including time for arrangement of the arm suspension and positioning of cuff and transducer. The system was calibrated daily just prior to each testing session. Subjects were instructed to relax in the suspension rig, and care was exercised to duplicate procedures daily. In an attempt to rule out effects of positioning and pressurization rates, a variety of techniques was explored, using ourselves as subjects. No significant differences were observed with repeated tests. Environmental temperature change, which is known to affect this measurement, was not controlled.

TREATMENT METHODS

Testing of the RGG was performed during the two middle weeks of the month-long bedrest study; actually, the four suited subjects were treated daily during the 15 days of actual bed rest. Two subjects were treated simultaneously in the morning (usually 08 to 12) and the other two were treated in the afternoon (1300-1700). Generally the Group I subjects (FF, DS) were the morning subjects; however, some shifting of morning and afternoon groups did occur to prevent interference with other test routines. The treatment log, including the daily treatment time, is given in Table 3. The suiting order, bed, and breathing system were rotated daily for each subject. The daily switching of breathing systems was introduced to eliminate effects that might result from slight differences existing in pressurization levels.

All RGG treatments occurred within the Human Research Facility at NASA Ames Research Center. A room separate from the subjects' normal bedrest station was used for this purpose. Subjects were delivered on wheeled hospital carts to the treatment room and weighed in the supine position before suiting began. Every second day the venous compliance test was performed on both the treated and the control subjects of a given group. The treated subjects were tested prior to dressing.

The dressing procedure, already outlined in the suit description section, at first required nearly 30 minutes, but by the end of the first week the time was down to approximately 15 minutes, including placement of the electrodes for the ECG. Treatment was considered to have begun when the helmet was in place. Usually pressurization of the system followed immediately. Each subject's treatment time was monitored by an electronic stopwatch. As can be seen by examination of Table 3, the treatment time after the 4th day was maintained at 210 minutes. This amount of time coincided with the established logistical routines. For safety, at least one monitor was always present in the room with the subjects.

Table 3.
Daily Treatment Log
Group I

<u>Day & date of bedrest</u>	<u>start time</u>	<u>Subject #1 -- FF</u>		<u>start time</u>	<u>Subject #4 -- DS</u>	
		<u>total treatment time (mins)</u>	<u>breathing system #</u>		<u>total treatment time (mins)</u>	<u>breathing system #</u>
1: 5/7/73	1300	109	1	1330	109	2
2: 5/8/73	0800	150	2	0830	150	1
3: 5/9/73	0830	160	1	0800	161	2
4: 5/10/73	0800	180	2	0830	180	1
5: 5/11/73	0830	210	1	0800	210	2
6: 5/12/73	0800	210	2	0830	210	1
7: 5/13/73	0830	210	1	0800	210	2
8: 5/14/73	1330	210	2	1300	210	1
9: 5/15/73	0800	210	1	0830	210	2
10: 5/16/73	0830	210	2	0800	210	1
11: 5/17/73	0800	210	1	0830	210	2
12: 5/18/73	0830	210	2	0800	210	1
13: 5/19/73	1300	210	1	1330	210	2
14: 5/20/73	0630	213	2	0700	212	1
15: 5/21/73	1330	210	1	1300	210	2

Table 3.
Daily Treatment Log
Group II

<u>Day & date of bedrest</u>	<u>Subject #7 -- JH</u>			<u>Subject #8 -- AH</u>		
	<u>start time</u>	<u>total treatment time (mins)</u>	<u>breathing system #</u>	<u>start time</u>	<u>total treatment time (mins)</u>	<u>breathing system #</u>
1: 5/8/73	1330	110	1	1300	110	2
2: 5/9/73	1300	151	2	1330	151	1
3: 5/10/73	1330	160	1	1300	160	2
4: 5/11/73	1300	180	2	1330	180	1
5: 5/12/73	1300	210	1	1330	210	2
6: 5/13/73	1330	210	2	1300	210	1
7: 5/14/73	0800	210	1	0830	210	2
8: 5/15/73	1330	210	2	1300	210	1
9: 5/16/73	1300	210	1	1330	210	2
10:5/17/73	1330	210	2	1300	210	1
11:5/18/73	1300	210	1	1330	210	2
12:5/19/73	0830	210	2	0800	210	1
13:5/20/73	1300	210	1	1330	210	2
14:5/21/73	0700	210	2	0630	210	1
15:5/22/73	1300	210	1	1330	210	2

As mentioned earlier, the entire dressing procedure was performed with the subject supine. When necessary, subjects were log-rolled to one side of the bed so that the garments could be positioned under them. Unavoidably the head had to be elevated slightly for donning the bubble helmet. Since the bedrest protocol allowed the subjects to move or elevate their arms, this freedom was also allowed during treatments. Occasionally some of the subjects preferred to support their hands on pillows. Often loose fitting stockings were worn. Disrobing, from depressurization to complete removal of the garment, required less than one minute.

Breathing pressure, heart rate, and electrocardiographic patterns (ECG) were recorded continuously throughout each treatment. In addition to recording, ECG's were monitored visually from the screen of a multichannel oscilloscope. ECG signals were detected by small disk electrodes (Beckman) which were located on the wrists and the right foot. This arrangement of electrodes produced patterns similar to the standard limb leads and permitted their application after the subjects were fully suited. Small preamplifier units were located on the beds. The ECG and recording equipment were furnished by the Human Research Facility. Periodically throughout each treatment suit counterpressure, blood pressure, and calf circumference measurements were taken. Calf circumferential (girth) change was used as a simple index of pooling at different breathing pressures. These data, along with observer and subject comments, were kept in individual log books.

Subjects were visually examined daily as part of the dressing procedure to determine the extent and location of any suit related trauma. Also subjects were quizzed to determine subjective response to the entire treatment procedure. Generally suit induced traumas were minimal and consisted of petechiae development in the supraclavicular region of the shoulder and occasionally in the antecubital folds. The petechiae in the first case resulted from reduced counterpressure to the area and in the second from fabric pinching with flexion. In no case were the effects alarming or progressive. Most cases were clear by the next treatment day. Fluid infiltration into tissues was not a problem. Markings on the skin from garment seams and bladder edges, although prominent immediately after undressing, usually cleared in a matter of a few hours after treatment.

Generally the subjects did not find the treatments physically objectionable; however, some compression of the abdominal wall by the bladder at the highest breathing pressure (100 mm Hg) made breathing difficult. Subjects quickly learned to produce neck seal leaks during the high pressure phase of the treatment in order to drop the pressure transiently to a more comfortable level. As a result, rapid pressure excursions from 100mm Hg down to as low as 20 mm Hg were not uncommon. We did not totally discourage this action, feeling that the type of pressure response produced was in line with the desired treatment program and would be good exercise for the vasculature. Pressure equalization in the middle ear did not appear to be a problem.

Various forms of diversionary activities were practiced to assist in the passage of time during the treatments. Perhaps the most common entertainment was color television. The TV was suspended over the bottom of the beds and angled so that viewing in the horizontal position was not difficult or uncomfortable. Often subjects would sleep or doze for periods of up to 1 hour or more. Newspaper reading was also common. Approximately mid-way through the 15 days of bed rest, a manually operated TV game (Magnavox) was obtained. Even though a variety of games requiring two persons could be played, interest dwindled after two days. Occasionally candies (Beech-Nut Life Savers, Inc., New York, N. Y.) were placed on the helmet microphone boom in a position accessible to the subject's tongue. Although most of the subjects enjoyed this treat, the practice was abandoned due to possible interference with biochemical test procedures.

RESULTS OF TREATMENT RELATED MEASUREMENTS

A great variety of physical and physiological tests was performed pre- and post-bed rest by several investigators. Basically, the physical test program was related to detecting decreases in orthostatic tolerance and exercise capability following bed rest and relating these to the relative effect of the RGG on prevention of the deconditioning process. The physiological tests included body composition studies and blood and urine biochemistries. In addition, routine metabolic ward data were collected. These tests and measurements and their results are to be reported elsewhere. In this report we deal only with those tests and measurements performed as part of the RGG treatment program.

Electrocardiographs and Heart Rate

Electrocardiographic patterns (ECG) were both recorded and visually displayed throughout each treatment session. The principal reason for monitoring the ECG's was as an on-line safety measure rather than for post-test analysis. It is fairly well established that pressure breathing may induce ECG pattern change, e. g. inverted T waves; however, the likelihood was reduced by application of torso counterpressure. Also, the bradycardia of impending syncope (from overpooling) or apprehensional tachycardia could be detected.

The strip chart ECG's from all of the treatment sessions have been examined. Not one example of an inverted T or premature ventricular contraction (PVC) was found. However, a degree of arrhythmia was observed in all subjects and at all pressures, which, although an R to R interval analysis was not made, appears to be greater than normally expected. The phenomenon appears to have been related to normal reflex responses that were accentuated

by the vascular pumping action during the respiratory cycle. The effect of increased myocardial storage of catecholamine products was not evident since the degree of tachycardia or arrhythmia did not change significantly during the 15 days of bedrest. Some shouldering on the descending limb of the QRS complex was observed in some of the records. This effect probably resulted from electrical axis rotation due to the pressure breathing.

Because of the RGG counterpressure gradient, a tachycardia similar to that observed in non-compensated positive pressure breathing was predicted. Ernsting (15) maintains that the magnitude of the increase in heart rate induced by pressure breathing depends upon the pressure level, the area to which counterpressure is applied, and the duration of exposure. Generally, the greater the pressure the higher the heart rate. The tachycardia probably results from reduced effective blood volume concomitant with reduced right heart filling pressure. If the RGG worked properly, we should have seen an increase in heart rate when the breathing pressure was at design gradient level pressure or above, and a low (or even reduced) rate at the lower breathing pressures. In order to determine whether this effect actually did occur during treatment, heart rates were counted from daily records for all four subjects. Because the breathing pressure varied, care was taken to select points that were stable. The average of ten counts per subject at each of four selected breathing pressure levels is plotted in Figure 17. A direct and essentially linear relationship between heart rate and breathing pressure was found. Using the mean value for all subjects, the difference between the selected pressure levels was greater with increasing pressure. A summary of the data is given below:

<u>Breathing pressure level</u>	<u>Average HR</u>	<u>Δ HR/level</u>	<u>HR range</u> (ind. aver.)
20-39 mm Hg	64.5 bpm	---	49.3-75.8 bpm
40-59 "	77.1 "	12.6 bpm	61.3-88.6 "
60-78 "	94.0 "	16.9 "	76.0-108.0 "
80-100 "	117.5 "	23.5 "	93.8-129.4 "

During a single breathing pressure cycle (25 to 100 mm Hg), the average increase in heart rate was nearly 53 bpm. Subject #4 was the most labile, showing an increase of 69.2 bpm over the pressure range. There was no evidence of increased ECG irregularities at the higher rates and higher pressures. If the increased rates observed at the higher pressures may be equated to cardiac exercise and if the reduced cardiac loads associated with weightlessness play a role in the deconditioning process, then it is fair to say that this mechanism should have been favorably affected by the RGG treatments.

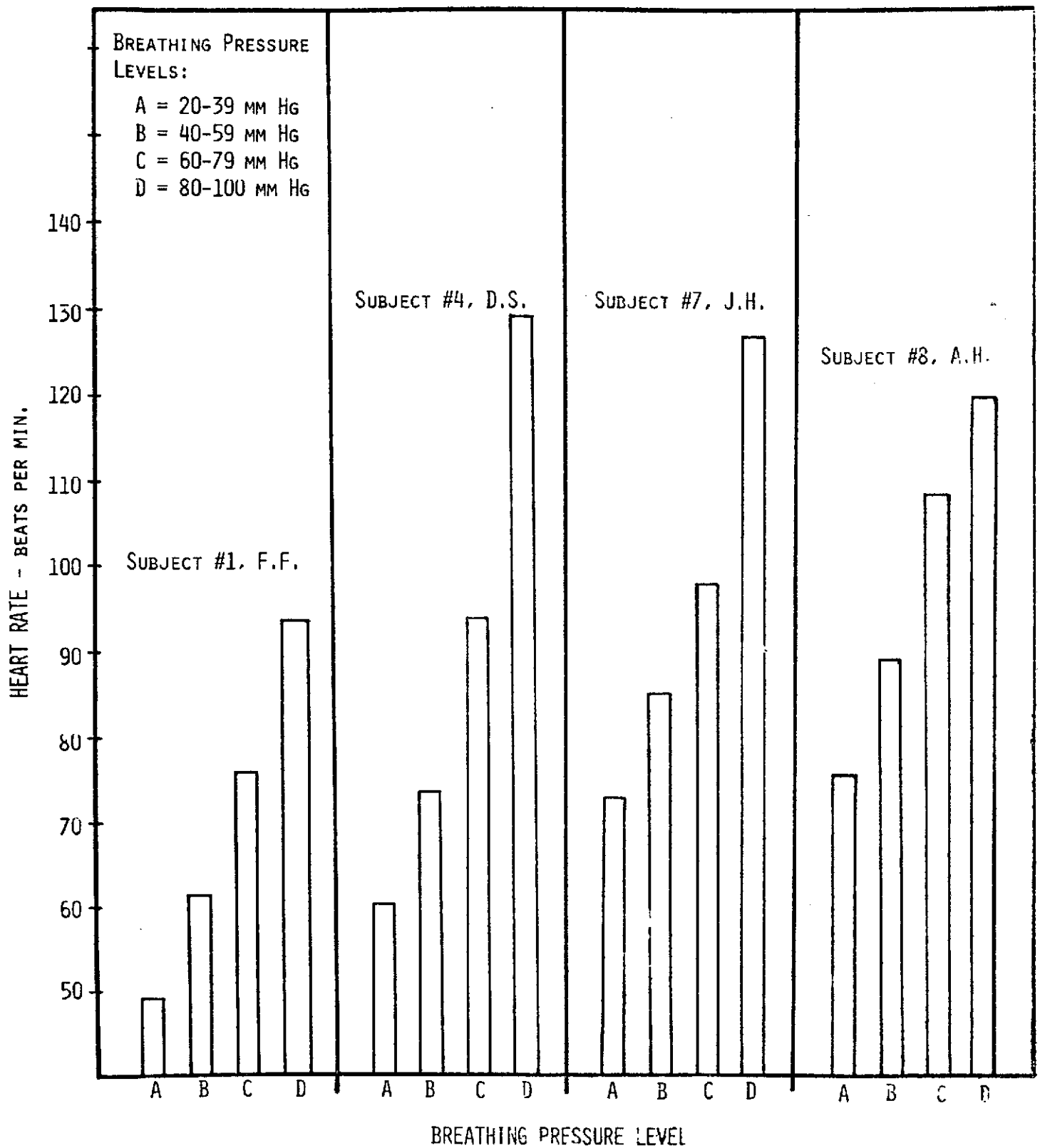


Figure 17. Effect of breathing pressure on heart rate. (Average of 10 data points per subject per breathing pressure level.)

Venous Compliance

Except for one day for each group (day 5, group 1; day 3, group 2), venous compliance measurements were made on both RGG treated and control subjects every second day of bed rest. The technique and equipment used have already been described. Since this was the only test of deconditioning done during the course of the bed rest, we relied upon it to reflect the degree of effectiveness of the RGG treatments. If, for example, an increase in compliance was observed after a few days in bed, in both suited and control subjects, we planned to intensify the treatment program. Unfortunately, however, this option did not occur, since significant changes in venous compliance were not observed in either group. The results of the successive measurements are plotted in terms of forearm girth change at 60 mm Hg cuff pressure in Fig. 18.

The data show a general tendency for the compliance to decrease during the first week of bed rest. From the 7th through the 15th day of bed rest, the values for the treated subjects cycled insignificantly; however, in the control subjects restoration of first day values occurred in all cases. Except for the initial decrease, the changes observed were probably within the error range of the instrument and are not considered significant. These results raise a number of questions, the first of which involves the accuracy of the technique. Because we were aware of possible inaccuracies, we took great care to check instrument function, calibration, and technique. We found no evidence of problems. We must assume, therefore, that the results obtained were valid. Why, then, was not an increase in venous compliance observed even in the control subjects, as would be predicted based upon results obtained in other weightlessness simulation studies (12)? One possible explanation may be related to differences in the deconditioning process when bed rest with or without water immersion is used as a simulant. Also, do veins become "flabby" and more compliant, or stiff and rigid and less compliant, as deconditioning progresses? Additional study is needed.

Tests of Garment Function

Tests of garment function including counterpressure measurements and calf girth measurements were performed during the treatment sessions. Counterpressure measurements were taken to verify the design pressure and gradients, and to determine whether the garment fabric would weaken as the result of daily donning fatigue (set), or if the original pressure would be diminished by loss of body mass. The technique and device used have already been described. Counterpressure measurements, always taken on the thigh and/or calf, were usually taken daily and recorded in the subject's log book. The results showed that not only were the pressure and gradients well within the ± 5 mm Hg design limits, but also that in 15 days of wear the decreases in pressure due either to fabric changes or loss of body mass were minimal for the areas sampled (the average of 60 measurements was -2 mm Hg).

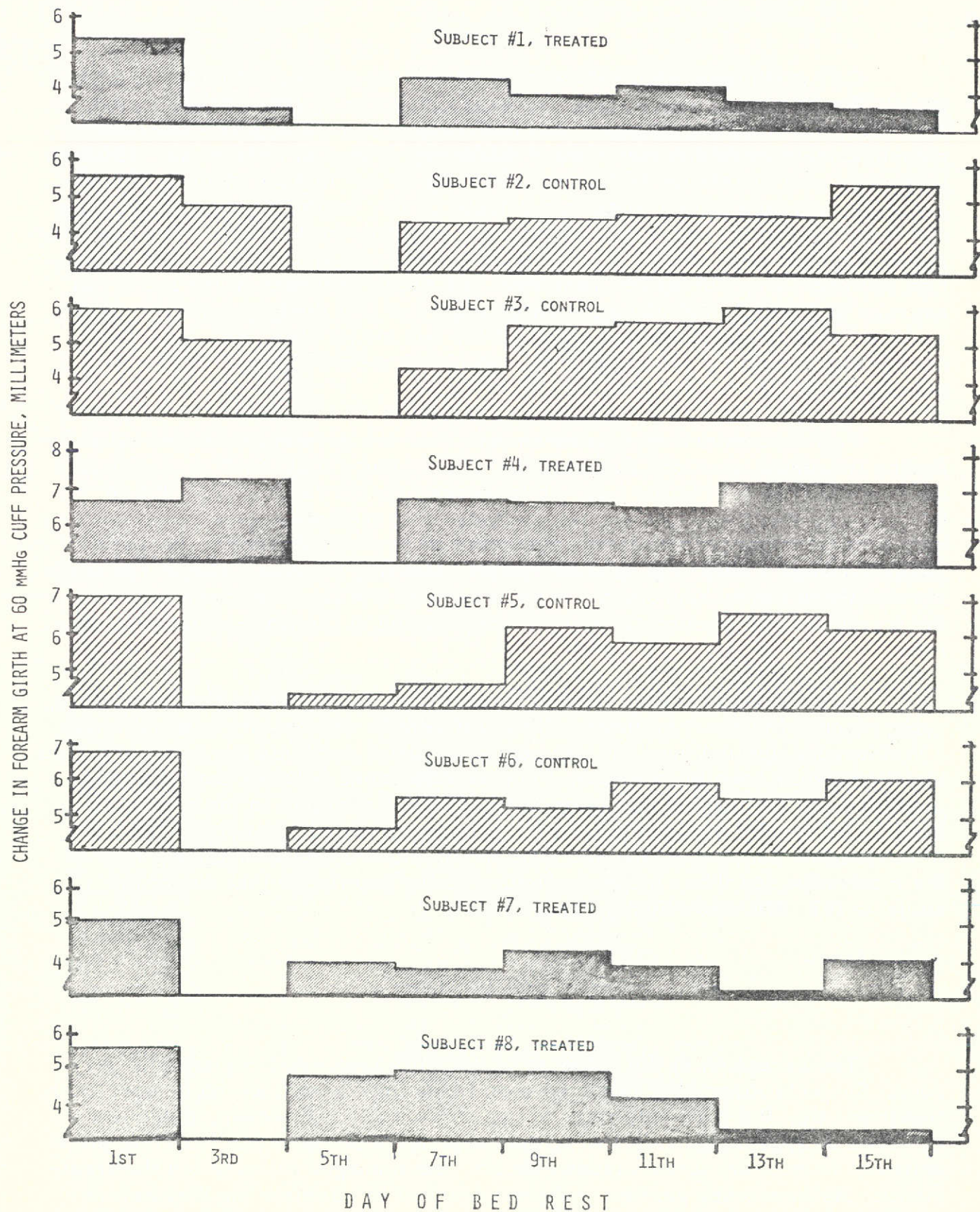


Figure 18. Venous compliance change over the 15 days of bed rest -- expressed as change in forearm girth at 60 mm Hg occlusion pressure.

Calf girth measurements were made on the treated subjects, using a small, flexible steel metric tape, several times during the bedrest period. Both nude and over-the-garment circumferences were obtained. The nude measurements were directed toward discovery of loss of body mass. Although there was some variation (± 0.5 mm) from day to day in each subject, no progressive decrease in calf girth was detected. The variability could have been due to measurement error and/or slight changes in the location of the measurement. Comparisons of calf circumferences obtained prior to garment construction to those taken during bed rest showed a slight decrease in the latter (an average of 0.4 cm), but other indications showed that design counterpressures were not significantly affected. Except for one subject (#8, AH), who lost nearly 2 kg during the testing period, total body weight changes were not significant.

Calf circumference measurements over the garment taken periodically during treatment sessions substantiated the evidence that the RGG was indeed causing blood to pool in the leg. An increase in girth ranging from 0.5 to 0.75 cm was found when early and late individual treatment session measurements were compared. These values compare favorably with the increase observed when a person goes from lying to standing position. There was some variability in the measurements associated with the actual elapsed time into the treatment and the breathing pressure existing at the time of the measurement.

Some blood pressure measurements were taken during the treatments, using standard clinical methods. Korotkoff sounds were easily detectable via a stethoscope applied over the garments. In order to obtain the true corrected blood pressure, one must subtract out the difference between the breathing pressure and the counter pressure applied by the garment to the antecubital area. The results of these measures are not presented, principally because of the limited number performed and the not unusual values obtained. Part of the motivation for these measurements was the knowledge that one of the subjects (#7, JH) was slightly hypertensive.

DISCUSSION

The reception of the subjects to the daily treatment regime was very good. Subjects invariably reported upon being quizzed immediately after each treatment that the garments were not uncomfortable. However, there was evidence of apprehension in two of the subjects. One found the isolating properties of helmet breathing claustrophobic, but managed to complete the treatments. As mentioned earlier, subjects learned to alleviate the discomfort associated with the high breathing pressure peak by inducing neck seal leaks.

This maneuver also tended to reduce crotch pull from helmet rise, which was also greatest at the highest pressure. To prevent hand pain resulting from engorgement with blood, three subjects routinely wore gloves that were made for this purpose. The fourth subject apparently did not find the hand pain intolerable and reported that the treatments had restored a full range of movement to an ankylosed finger joint. Loose fitting athletic stockings were worn only to prevent cold feet. Considerable pain in the antecubital area of the arm was experienced by several of the subjects on days in which RGG treatments followed the venipunctures performed in connection with glucose tolerance tests. To alleviate this problem, the garments were slit open over the affected arm. Hematomas, which would definitely be aggravated by the treatments, never became a problem. Petechiae formation resulting from pinching or low counterpressurization were not remarkable. An itching sensation in one subject thought to be a reaction to the elastic fabric was corrected by a liberal application of talcum powder prior to dressing.

The design and construction of the RGG's used in this study were preliminary and specifically oriented toward a test situation. A number of design approaches were open to us, the most attractive of which was a more or less constant wear garment in which the counterpressure engineering of the elastic fabric would have been minimal. However, in production the gradient producing device would have become more complex. For example, the power of the selected fabric could be played against an internal bladder system which, when inflated to a specific pressure, would produce the desired gradient. Or, a gradient of pressure could be obtained by combining a variable take-up capstan with non-stretch fabric. This technique, we understand, has been developed for a direct gradient support stocking used post-mission by Apollo 20 and Skylab astronauts. Both of these approaches are very attractive, although the "plumbing" is complex. When all trade-offs were considered, the approach we took seemed more appropriate at this stage of development. The obvious disadvantages of the completely elastic fabric supplied counterpressure involve the difficulty of donning and the lack of the constant wear feature. The advantages of the elastic supplied counterpressure are simplicity and reliability. This, however, is not the form we would recommend for space flight. A flight version should be capable of being worn unpressurized. During treatments, the astronaut would put on a helmet, pressurize the system, and continue his work assignments. The type of garment would probably involve the use of a gradient producing capstan arrangement.

It is our belief that the RGG used in this study functioned as intended. However, as indicated earlier, we had relied on the venous compliance test to demonstrate the separation in deconditioning between the treated and control subjects during the course of the bedrest. Since this separation did not occur, the option to intensify or change the treatment program was not given us. Collateral tests should have been scheduled near the midpoint of the bed rest. An LBNP test on the 7th day would have been useful.

At this writing it is not clear how effective the RG was in limiting cardiovascular deconditioning. The data are currently being analyzed. It is clear, however, that the RGG did not totally prevent deconditioning. The relative amount of deconditioning appears to be somewhat individual. Whether the sue of the dynamic treatment schedule or the reduced time spent during each treatment at full hydrostatic pressure (100 mm Hg) may have acted to reduce the effectiveness of the RGG cannot be answered at this time.

APPENDIX A.

Rationale for a Dynamic Treatment Regime with the Reverse Gradient Garment

Since one of the most obvious stressors diminished by weightlessness (or recumbency) is the hydrostatic force imposed on the vascular system at 1 g, the conclusion follows that in order to be an effective countermeasure to cardiovascular deconditioning the Reverse Gradient Garment (RGG) must in some measure restore these conditions. The etiology of weightless-induced cardiovascular deconditioning is not known; however, it is through the venous system that the effects of gravity upon the circulation are most evident. It is well established both by direct and indirect measurement that the venous pressure at ankle level in the quietly standing man may reach 100 mm Hg. Because of this fact it has been the opinion that the RGG must recreate a 100 mm Hg venous pressure at the ankle in order to be effective. In a successful study of the principle of the reverse gradient countermeasure conducted by Webb Associates in 1966 (12), the selected nominal pressure gradient was 100 mm Hg. The maximum 100 mm Hg gradient, however, was applied to the test subject in any significant degree only during the second week of a 2-week weightlessness simulation study. The Cardiovascular Conditioning Suit did, during this period, nearly restore pre-deconditioning cardiovascular fitness levels as shown by a number of measurement techniques. The actual number of hours per day spent by the subject during the second week of the test at the nominal pressure varied from two to four; however, rarely was the full 100 mm Hg pressure applied continuously for the entire treatment period. Also during each treatment period the breathing pressure often cycled over quite a wide range. Our present thinking led to the concept that it was not so much the level of the pressure which effected the reconditioning but rather the cycling of pressures.

The "parade ground faint" is a real orthostatic phenomenon which is not often experienced in ordinary life since only rarely does one stand quietly for more than a few minutes. The slightest muscular contraction and perhaps even muscle tremor serve to promote venous return. During activity such as walking, venous pressure at the ankle is dropped significantly. Even during isotonic contractions in which venous pressure is transiently elevated in the muscle, blood flow in the veins is directed by the valves toward the right heart ("muscle pump" or "venous pump"). The fit man, who may not show any more orthostatic tolerance than his sedentary brothers, is active and periods of full hydrostatic pressure effects are short as venous pressure and its effects on maintenance of venous tone fluctuate over a wide range with a highly variable period. Astronauts for the foreseeable future will be fit men who are used to being active and have not pre-adapted their cardiovascular system to hydrostatic pooling effects that may be associated with a more sedentary life style.

Attempts to estimate the time-pressure profile of venous pressure at various locations in the body over a normal day's routine are most difficult, since the profile is as variable as an individual's activity-inactivity while sitting, standing, and lying down. The best approach, therefore, in establishing an RGG pressure treatment regime is first to examine the fluctuations in venous pressure at the most hydrostatically affected point (foot-ankle) and, second, attempt to fix the time relationships of pressure variation. Some physiology textbooks are not clear about venous pressure fluctuations at the ankle with exercise; however, Barron (18) quotes an average value of 22 mm Hg (range 11 to 31 mm Hg) during walking, and Guyton (19) gives a value of 25 mm Hg (no range quoted) for a walking adult. In the Handbook of Physiology, Guyton (20) says the venous pressure at the ankle may be 20 to 25 mm Hg in a walking man.

By indirect measurement Beecher, et al (21) found a mean venous pressure at the ankle during stepping of nearly 32 mm Hg with a single step cycle range from 50 down to 22 mm Hg. Approximately 2/3 of the cycle time venous pressure was below the mean. Pollack and Wood (22), using a direct measurement technique, quote a mean venous pressure of 22 mm Hg in subjects walking at 1.7 mph. Only slight increases in the mean pressure were observed at faster walking speeds. During quiet standing the average pressure at the same site and for the same subjects was 86.6 mm Hg--nearly the value predicted by calculation of hydrostatic column heights. Single step pressure swings and continuous walking equilibrium values are also given by Pollack and Wood. After an initial peak pressure spike of approximately 100 mm Hg, which occurs as the foot leaves the ground on the first step, the pressure falls rapidly to reach a steady step cycle amplitude of approximately 15 mm Hg (range 15-30 mm Hg). A certain amount of damping in the various measurement systems will only allow one to estimate peak pressure fluctuations; however, it is quite clear that movement related pressure changes exceed the quoted values.

It is understood that vascular dynamics are complex and weightlessness induced cardiovascular deconditioning may involve loss or shifting of blood volume, adaptive changes in the response of neurochemical mechanisms, changes in vascular and valvular tone or elasticity, and other contributing factors, which are not necessarily restricted to the cardiovascular system. Regardless of cause complexity and the resulting symptoms, the most debilitating effect is expressed as orthostatic intolerance, which in the final analysis must be a vascular phenomenon. We believed cardiovascular deconditioning could be prevented by an RGG treatment program which best typified the factors of daily living as they are expressed through pressure fluctuations in the veins. We, therefore, chose the following treatment approach:

1. The daily treatment period for test subjects should not be less than 3 hours, and, because of logistics, subject tolerance, and other factors, the treatment period probably should not exceed 4 hours per man per day.
2. Subject torso pressurization via bladders connected to the breathing system should be cycled rather than a continuous single pressure.
3. Suit gradients should be designed so that the reverse gradient on the limbs is matched with 50 mm Hg pressure applied by the breathing system during the primary pressurization period which is constant and amounts to one-half of the total treatment time.
4. The range of the pressure swings during the other half of the treatment should be of the same order as those observed in the ankle veins with erect exercise, e. g. 20 to 100 mm Hg, and applied briefly on a regular schedule.
5. The timing of the pressure cycles should be based in part on the periodicity observed with walking and adjusted for the subject's ability to tolerate pressure changes in the helmet both for equalization and ease of respiration. Times spent at pressure extremes should be long enough to produce the desired effect, yet short enough to preclude "overpooling" or significant loss of fluid into the tissues.
6. There should be no attempt to cycle limb gradients in the suit to match pressure swings in the helmet. This would be difficult to accomplish accurately and would not be desirable if we were to obtain maximum vascular stresses. When breathing pressure is above the garment gradient on the limbs, "hydrostatic pooling" should occur. When breathing pressure is below the highest counterpressure in the limbs, the effect should be occlusive and similar to the sometimes beneficial countermeasure using limb cuffs. The purpose of this maneuver is, however, principally directed at forced closure of venous valves in the limbs distal to the most occlusive point, e. g. thigh. With breathing pressure matched to the garment design gradient, the valves receive no exercise, since the ΔP across the heart is not grossly changed nor is the pressure drop across the vascular bed affected. Therefore, to insure valvular exercise, which we felt was important in the maintenance of valvular tone, a "sub-gradient" breathing pressure was included in the treatment regime.

The pressure schedule chosen is described on pages 16 to 18 of the main text.

APPENDIX B.

Development of an Improved Power-Net Fabric for Use in a Reverse Gradient Garment

Prepared by Robert Donnelly, Prodesco, Inc.
January 1973

Abstract

This report describes the fabrication and properties of a series of power-net fabrics developed under purchase order number RGG 92572. The fabrics developed and produced have improved properties for use in reverse gradient garments.

The final fabric delivered (5143 001, sample #4G) exhibited the following properties:

Weight:	8.1 oz/sq. yd.
% elongation at 10 lbs/inch:	174 x 148 (w x c)
5 lbs/inch:	115 x 115 (w x c)
1.6 lbs/inch:	31 x 51 (w x c)
Opening at maximum tension:	1.0 mm ²
Air permeability:	335 ft ³ /ft ² /minute
Thickness:	.034 inches
% Nomex	68
% Lycra	32

These specifications represent the results of utilizing a known fabric making process. Variations to that process will influence all the above properties; therefore, fabrics can be designed with as many different physical properties as required in the RGG.

Introduction

A power-net construction made from spun Nomex and Lycra spandex yarns was developed to meet the customer's requirements for elongation/load properties. The potential exists, through judicious selection of material and process techniques, to produce precisely engineered fabrics that will exert almost any combination of modulus, stretch and weight.

Utilizing those yarns and power-net fabrication procedures, fourteen variants were produced. An improved version of Sample #4 was made using Sage Green Nomex in place of Natural Nomex. All technology used for this program is current state-of-the-art in the textile industry.

Technical Discussion

Materials/Yarns

Non-elastomeric component. --In general practice for power-net fabrics, the hard (non-elastic) component is usually 1/5 to 1/10 the denier of the elastomer component. The finest (lightest weight) Nomex available was selected for the first series of fabrics. It was a 50/1 cotton count natural (white) Nomex yarn. In order to speed the progress of the program, the yarn was selected from Prodesco stock. There were no provisions in this program to develop a Nomex yarn.

A second fabric was made utilizing a combination of 50/1 and 40/1 solution dyed sage green Nomex yarn. This yarn was selected to improve fabric quality and strength.

Nomex is available from the fiber producer in three colors other than natural. They are: international orange, olive green (to match Army color OG-106), and sage green. Nomex is also available in a dyeable fiber for a greater range of colors. We do not feel that the aesthetics or color of this fabric was important for this program at this point.

Spandex component. --The spandex component of the fabric selected was 840 denier, Type 126 Lycra (E. I. duPont de Nemours registered trademark for its segmented polyurethane spandex fiber). It is the most widely used spandex in power-net and was used in prior work by Webb Associates. Type 126 indicates an improved yarn over the original with regard to light stability.

Lycra is available in deniers ranging from 20 up to 2240, which was used in the "power-net" reported previously. That fabric was reported to have too much power, so 840 denier was selected. It turned out to be a sound choice because the elongation properties targeted (150%) were met.

The Lycra was not wrapped by any yarn prior to fabrication. This was listed as an option in our proposal, and would have been included in the fabrication had we not been able to meet the fabric requirements otherwise. It is an added expense in fabricating power-net fabrics and it is done to assist in knitting and in hiding the spandex so that it does not show in certain constructions.

Warping Conditions

Nomex. --The 50/1 natural Nomex yarn was wound onto 168 cones, each with 6000 yards of yarn. These cones were set up onto our direct warp creel.

Six warp beams were made, each 168 ends, 7 inches wide, and 900 yards in length. This was a total of 1008 Nomex ends for knitting on the Raschel machine.

The sage green Nomex, both 50/1 and 40/1, were wound onto 84 cones each 4400 yards long. These cones were tied onto our direct warping creel.

Six beams were made, each having 84 ends at 700 yards long, for a total of 504 ends for the 50/1 sage green and also for the 40/1 sage green. A total of 1008 ends distributed one of 40/1 and one of 50/1 were used for knitting the second fabric on the Raschel machine.

Spandex warp.--The Lycra yarn purchased from Du Pont was warped onto a knitting beam at the facilities of Vetex Manufacturing Co. in Allentown, Pa. This company is equipped for handling rubber and spandex yarns on a two-stage power creel warper. This device uses a surface drive to control the yarn.

The warp contained 1008 ends of 842 denier Lycra warped at 90% elongation. This elongation is normal for handling spandex yarns, but could have been increased to impart additional power to the fabric if required. Fabric tests showed that changing the warping elongation was not necessary.

Knitting Machine Description

The machine used to knit all the fabrics described in this report is a 48 gauge (24 needles per inch) Kidde model E-10, 10 guide bar, equipped with negative warp let off. This machine runs at approximately 200 stitches/min.

After the fabric is knit at the needles, it passes between several rolls, which pull the cloth at a rate in relationship to the knitting speed. The number of stitches per inch in the knit fabric can be varied by changing the gear ratio between the cloth take up and the machine drive. The term "quality" is used to define this fabric making condition. These will be described in more detail in the section, below, called "Knitting Condition Variations."

Fabric Construction Description

Typical power-net construction relies upon the non-elastic or hard fiber knitting yarns to interloop to form a knitted mesh structure into which the spandex is introduced in the lengthwise direction. There are an equal number of spandex and hard yarns in a given inch of power-net fabric. The spandex does not knit but merely "lays-in" during the knitting. The following figures #1 and #2 have been extracted from Du Pont Technical Bulletin L-61. They illustrate: 1) the looping motion of the hard fiber and the laying-in of the spandex; and 2) the motions of the guide bars required to make the power-net structure.

The samples made in this program were all knit according to those patterns.

At this point in the program, it was not necessary to change the power-net construction from that used in previous SAS garments. Webb Associates should be aware, however, that the stitch pattern can be changed if necessary for future fabric development.

As can be seen by examining the green fabric (sample #4), there is more Nomex yarn showing on the face of the fabric than on the back. This characteristic allows the Lycra to "grin through" on the back. We do not feel that this is objectionable in this particular case.

The stretch and recovery in the fabric comes entirely from the Lycra yarns; however, the Nomex not only contains the Lycra but also controls the amount of elongation and recovery allowable. Changing the condition under which the fabric is knitted substantially changes the fabric properties as described in the following section.

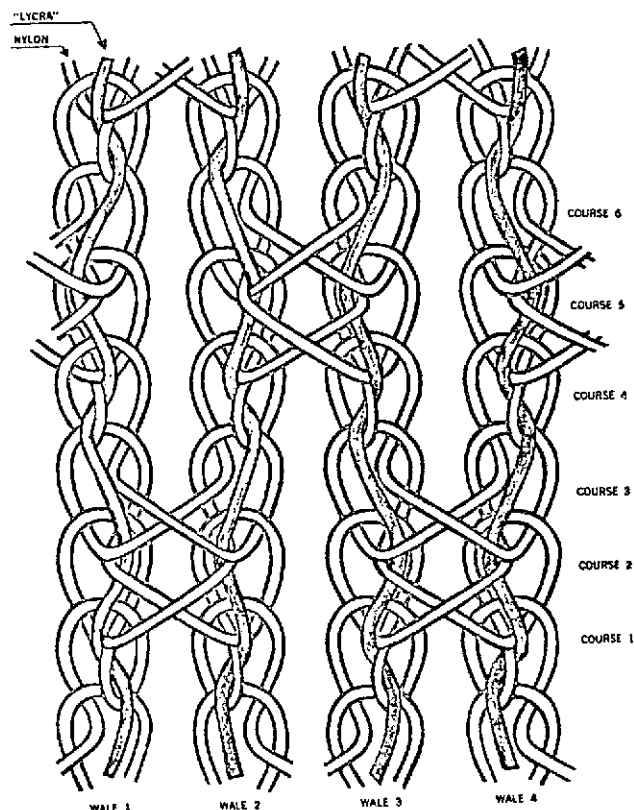


Figure 1. Power-Net Diagram.

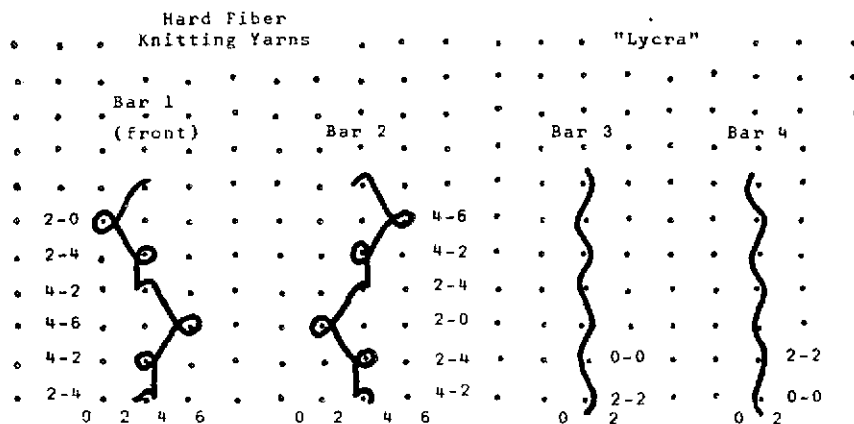


Figure 2. Raschel Power-Net Lap Diagram.

Knitting Condition Variations

There are three variables that can be introduced into power-net fabrication on the knitting machine. They are: 1) tension on spandex; 2) amount of hard yarn run-in; and 3) number of stitches per inch or "quality." Couple these variables with those mentioned before, i. e. yarn deniers, spandex warping tensions, knitting machine gauge, and knitting pattern. These variables multiplied by the property changes which are effected by fabric finishing, produce an almost infinite number of fabric stretch properties. The experience of the fabric designer and finisher is important in selecting the proper combination of variable conditions to "zero-in" on fabric requirements.

For instance, the run-in length--that is, the inches of hard fiber yarn per 480 stitches (expressed as x inches runner length)--has primary control of elongation and power of the fabric in the machine direction. An increase in the hard fiber runner length will increase the fabric elongation. This is because the hard fiber is not knitting around the spandex as tightly and allows it to recover some of the elongation that has been removed during processing to the point of knitting. Other results are: decrease in fabric power and a slight decrease in fabric width elongation.

An increase in the knitting tension on the spandex will cause a significant decrease in width elongation, a slight increase in warp elongation, and a slight decrease in power. This is because as you increase the tension on the spandex, you continue to remove available elongation and lock that elongation out of the fabric by the hard yarn stitches "jamming" on each other as the fabric relaxes.

The number of openings per square inch in the fabric is influenced by the fabric take up or "quality." It is also influenced by tension on the spandex. However, if a given set of conditions such as spandex tension and runner length do not result in desired fabric properties, a change made in the knitting quality will move these previous conditions into another area of fabric properties. As an example, the curves plotted by Du Pont in Technical Bulletin L-61 (Figure 3, below), show the variables possible in length elongation by changing nylon runner length and/or Lycra tension.

Knitting Conditions for 5143 001

<u>Sample #</u>	<u>Quality (Inches per 480 stitches)</u>	<u>Runner Length (Inches per 480 stitches)</u>	<u>Lycra Tension (Grams/Denier)</u>
1	8	52	.0137
2	6	44	.0155
3	6	44	.0570
4 & 4G	8	50	.0417

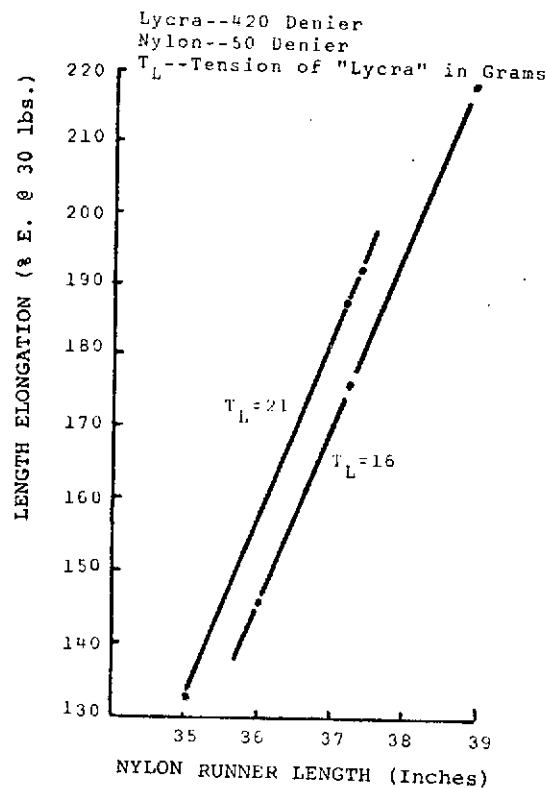


Figure 3. Effect on length elongation of nylon runner length.

Fabric Finishing Variations

Stabilizing fabrics containing spandex yarns can best be accomplished by heat-setting them under controlled conditions. Lycra fabrics are generally stabilized at temperatures ranging from 360° to 390°F, and at exposure times varying up to 90 seconds.

A wet set treatment consisting of immersion in very hot (200°) water and immediately quenching in cold water will also stabilize fabrics containing spandex. This procedure is less controllable and is only used when fabric shrinkage is required. Heat-setting fabrics on tentering equipment where control of both the length and the width of the fabric is possible, is a more desirable procedure.

If it is desired to remove elongation, for instance 25% from a fabric with a 175%, it is possible to accomplish this by pulling the fabric 35% during heat-setting. A certain amount of molecular reorientation takes place in the spandex polymer during heat-setting, and the fiber will take on new stress strain properties after heat-setting.

In this program, heat-setting was used as "fine tuning" for the fabric properties. The samples were tested as they came off the knitting machine and elongations recorded. Then the same fabrics were finished under various conditions and the elongations recorded.

Various finishing tests were evaluated in the finishing laboratory on small samples. They are described as follows:

Procedure A -- Wet set (dipped in boiling, then in cold water relaxed) and scoured (190°F water for 5 minutes, then dried)

Procedure B -- Heat set in dry air at 390°F for 90 seconds (fabric relaxed on frame)

Procedure C -- Wet set only

Procedure D -- Wet set, then dry heat set as in "B"

These laboratory finishing experiments were made to establish certain data points with relation to their effect upon the first three samples. A cross reference chart of elongation data was generated and is reported in the next section.

Testing for Load/Elongation

Test procedure. --The test procedure is described in Federal Standard CCC-T-191 under method 4106. The test apparatus was a Scott Model IP4 Serigraph, constant rate of load testing machine equipped with automatic cycling and a counter.

Whenever possible specimens were cut from both the wale (machine direction) and course (cross machine direction) of the fabric. By doing this, we were able to determine the effect of variables on both directions.

The machine was equipped with a 30 pound load which would give a loading force of 4540 grams per inch of fabric. As described in the test specification, only the fifth load cycle was used for reporting purposes. The machine made one test cycle in approximately 40 seconds.

Another data item recorded was the "set" of the fabric. This is the distance between point zero on the chart and the point to which the fabric has recovered before loading on the next cycle. This number is indicative of the capability of the fabric to recover from a load as quickly as that load is removed. Although this information was not required, we felt that it could be important in choosing between certain fabrics.

Sample test results. --The first three fabrics were finished according to the four procedures described above and tested in both the wale and course direction. The following table lists the elongation at 10 pounds per inch load for all fabric samples and also the per cent of nonrecovered elongation on each sample.

Sample Test Results

% elongation at 10 pound/inch load

<u>Finish</u>	Sample 1 <u>W x C</u>	Sample 2 <u>W x C</u>	Sample 3 <u>W x C</u>
None	76-196	66-162	98-94
A	142-196	82-166	118-94
B	156-191	90-158	122-95
C	90-192	68-135	114-88
D	104- X	82-178	128-90

(X = ran off chart)

% elongation not recovered (set)

<u>Finish</u>	<u>Sample 1</u> <u>W x C</u>	<u>Sample 2</u> <u>W x C</u>	<u>Sample 3</u> <u>W x C</u>
None	6 - 42	5 - 20	2 - 17
A	7 - 23	5 - 13	5 - 18
B	7 - 21	5 - 16	5 - 16
C	4 - 24	4 - 9	5 - 16
D	6 - X	5 - 19	6 - 14

(X = not measured)

The desired elongation of 150% came closest to being achieved by the wale direction of sample #1 and the course direction of sample #2. Also, we were able to achieve an increase in the wale direction elongation through all of the relaxed fabric finishing procedures. Procedure B (heat-setting only) appeared to be the most effective in controlling the Lycra elongation.

An additional sample (#4) was knit using variations from the first three knitting conditions. They were: quality--8 inches as in sample #1; hard yarn runner length--50 inches as in sample #1; and Lycra tension--0.417 grams per denier. We felt that this would keep the wale direction elongation essentially the same as sample #1 and would increase the power, thus reducing the elongation in the course direction as in sample #2. It was also desirable to reduce the fabric set as much as possible.

The sample was heat-set, allowing the length to shrink, and holding the width as it came off the machine. The results of the elongation tests are :

Sample 4 Test Results

	<u>Off Machine</u> <u>W x C</u>	<u>Finished</u> <u>W x C</u>
% elongation at 10 lbs.	113-164	164-159
% elongation retained (set)	5-26	16-24

A duplicate of sample #4 was made using sage green yarns described above. This fabric was made because the overall defect level of sample #4 was too high to be acceptable and the tearing strength seemed questionable to Webb Associates. The test results off machine, and lab sample finished, are listed in the following table.

Sample 4 "G" Test Results

	<u>Off Machine</u> <u>W x C</u>	<u>Finished</u> <u>W x C</u>
% elongation at 10 lbs.	127-176	162-163
% elongation retained (set)	7-20	8-14

The green fabric exhibited a vastly improved defect level over the white development samples. An average of one defect per yard was observed during the inspection.

Other fabric properties are listed below. We have run a comparison with the white sample wherever feasible.

Comparative Fabric Properties

(5143 001, Sample #4)

	<u>White</u>	<u>Green</u>
Weight (oz/yd ²)	7.8	8.1
Air permeability (ft ³ /ft ² /min)	312	335
Thickness (inches)	.033	.034
% Nomex	59	68
% Lycra	41	32

Prototype yardage was heat-set on a "Famatex" tenting frame at 390°F for 45 seconds. The fabric was pulled 5% in the width and overfed 1% in length. The construction changed from 34 wales per inch off machine to 32.5 finished.

Conclusions and Recommendations

As a result of the reported program, we can make the following conclusions:

1. Spun Nomex and filament Lycra are compatible in power-net constructions.
2. A quality improvement can be realized in the fabric by utilizing better quality yarns.
3. A fabric that exhibits equal or balanced elongations is possible.
4. Spun Nomex provides a soft, warm "hand" for intimate wear.

We make the following recommendations for consideration by Webb Associates:

1. A fabric with a "nap" be evaluated.
2. Elastomers other than "Lycra" be evaluated, for flame retardancy.
3. A "stockpile" of power-net fabrics be prepared, each having properties suitable to a given body segment.

APPENDIX C.

Physical Properties of the 100% Nomex Fabric (non-stretch) Used in RGG Construction

	<u>Minimum</u>
Weight: (oz/sq. yd.)	5.0
Thread count	90 x 88
Breaking strength (lbs)	warp x filling 100 x 100
Tearing strength (lbs)	warp x filling 15 x 15
Air permeability (cubic feet/square feet/ minute)	100

APPENDIX D.

Computer Program

Fabric "cut-lengths" to supply a given counterpressure
for a range of circumferences.

FORTTRAN IV	MODEL 44 PS	VERSION 3, LEVEL 3	DATE 73052
0001	1	DIMENSION BLANK(1),CIR(400),BLNK(1),PRESS(100),CUTL(400)	
0002		M=0	
0003		CIR(M)=3.9	
0004		DO 2 I=1,360	
0005		CIR(I)=CIR(I-1)+0.1	
0006		PRESS(M)=-0.01934	
0007		DO 4 J=1,51	
0008		PRESS(J)=PRESS(J-1)+0.01934	
0009		TEN=(PRESS(J)*CIR(I)/6.28)*2.0	
0010		ELONG=0.18083*TEN	
0011		IF(TEN-0.83) 4,4,30	
0012	30	ELONG =0.3428*TEN-0.14	
0013		IF(TEN-2.90) 4,4,40	
0014	40	ELONG=0.11428*TEN+0.52	
0015	4	CUTL(J)=CIR(I)/(1+ELONG)	
0016		CIR(I)=CIR(I)*2.54	
0017		DO 6 K=1,51	
0018		CUTL(K)=CUTL(K)*2.54	
0019	6	PRESS(K)=PRESS(K)*51.714	
0020		WRITE(6,14) CIR(I)	
0021	14	FORMAT(5X,5X,7HCIRCUM#,F8.2)	
0022		WRITE(6,24)	
0023	24	FORMAT(18X,8HPRESSURE,5X,10HCUT-LENGTH,10X,8HPRESSURE *10HCUT-LENGTH)	
0024		DO 12 L=1,25	
0025	12	WRITE(6,34) PRESS(L),CUTL(L),PRESS(L+25),CUTL(L+25)	
0026	34	FORMAT(20X,F6.2,8X,F7.2,12X,F6.2,8X,F7.2)	
0027		WRITE(6,60)	
0028	60	FORMAT(/,1H)	
0029		CIR(I)=CIR(I)/2.54	
0030	2	CONTINUE	
0031		STOP	
0032		END	

APPENDIX E.

List of Tests Performed on Subjects

A. Orthostatic Tolerance

1. Centrifugation, time tolerance at 2.5, 3.0, 2.5 G, +G_z
2. Lower body negative pressure (LBNP), 50 mm Hg, 15 mins.

B. Exercise Tolerance

1. Maximum O₂ uptake, heart rate response to work; bicycle ergometer

C. Body Composition

1. Total body water (D₂O)
2. Total body potassium (40K)
3. Extracellular fluid space (14C-sucrose)
4. Plasma volume (T-1824)
5. Red cell volume (51 Cr)
6. Venous hematocrit
7. Fluid balance (intake-output)
8. Body weight (daily)

D. Blood Biochemistries

1. Insulin response to glucose
2. Hemoglobin
3. Plasma electrolytes (K, Ca, Na, Mg, Cl)
4. Plasma protein and electrophoretogram
5. Plasma lactate dehydrogenase & electrophoretogram
6. " alkaline phosphatase and "
7. " glutamate-oxalate transaminase
8. " glutamate-pyruvate transaminase
9. Dopamine-B-hydroxylase (DBH)

E. Urine Biochemistries

- | | |
|---|---------------------------------|
| 1. Volume | 10. Citrate |
| 2. Specific gravity | 11. Aldosterone--ADH |
| 3. Total osmotic pressure | 12. Cortisol/ACTH |
| 4. Electrolytes (K, Na, Ca, Mg, Cl, PO ₄) | 13. Epinephrine, norepinephrine |
| 5. Total nitrogen | 14. Dopamine |
| 6. Creatinine | 15. 17-OHCS |
| 7. Creatine | 16. Cyclic AMP |
| 8. Hydroxyproline | 17. Cyclic GMP |
| 9. Glucose | |

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